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Atlantic Design Engineers, Inc.
P.O. Box 1051
Sandwich, MA 02563

PERFORMANCE TEST REPORT

Chamber Exhaust Vent - May 20, 2019

Chamber S8 and S9 Back Vent Controls

Cook Sterilization Facility
Ellettsville, Indiana

Prepared For:

Cook Incorporated
6300 North Matthews Drive
Ellettsville, Indiana 47429

ADE Project No. 5450.12

August 28, 2019

[redacted]

CONTACT SUMMARY

CLIENT CONTACTS

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PERFORMANCE TEST CERTIFICATION

1. Certification of test report and calculations by the team leader of the personnel conducting the sampling procedures and test report author:

"I certify that the analytical procedures and data presented in this test report are, to the best of my knowledge and belief, true, accurate, and complete."

[redacted]	Asa Smith
Signature	*Printed Name of Person Signing*
Senior Environmental Engineer	8/28/2019
Title	*Date*

2. Certification of calculations and sampling procedures by the person responsible for project QA/QC:

"I certify that the calculations were performed in accordance with the requirements of the test methods and that the data presented for use in the test report were, to the best of my knowledge and belief, true, accurate, and complete."

[redacted]	Zachary T. Thomas
Signature	*Printed Name of Person Signing*
Project Manager	8/28/2019
Title	*Date*

3. Certification of test report by the senior staff person at the testing company who is responsible for compiling and checking the test report:

"I certify that this test report and all attachments were prepared under my direction or supervision in accordance with the project test protocol and that qualified personnel properly gathered and evaluated the test information submitted. Based on my inquiry of the person or persons who performed sampling and analysis relating to the performance test, the information submitted in this test report is, to the best of my knowledge and belief, true, accurate, and complete."

[redacted]	Simon B. Thomas
Signature	*Printed Name of Person Signing*
Principal	8/28/2019
Title	*Date*

1.0 PERFORMANCE TEST SUMMARY

Cook, Inc. (Cook) manufactures medical products at its Ellettsville North Sterilization Facility located in Ellettsville, Indiana (Ellettsville North). Heat sensitive medical products are sterilized following manufacture before distribution to the marketplace. Since some products are heat sensitive, a low temperature Ethylene Oxide (EtO) gas sterilization process is used to produce and guarantee sterility without affecting product integrity.

Ellettsville North existing sterilization operations consist of nine (9) sterilizer chambers designated as Sterilizers S1 through S9, fourteen (14) aeration rooms (hot cells HC1 through HC14), and associated emissions control equipment. The existing facility uses pure EtO gas as sterilant gasses. The facility operates in accordance with a Federally Enforceable State Operating Permit (FESOP) Renewal F105-27381-00030 issued by the Indiana Department of Environmental management, office of Air Quality (IDEM) on August 24, 2009. Two Significant Permit Modifications have since been issued by IDEM; the first Significant Modification (F105-29042-00030) was issued on June 25, 2010 and a second Significant Modification (F105-32055-00030) was issued on September 7, 2012 for the addition Sterilizers S8 & S9.

To achieve further reductions in its facility EtO emissions, Cook elected to modify the existing FESOP to voluntarily install additional emissions controls for the chamber exhaust vents (back vents) associated with Sterilizer S8 & Sterilizer S9. Accordingly, an Administrative Amendment was submitted to IDEM on December 31, 2018 to install three dedicated DR490 dry bed reactors to control back vent emissions from the two sterilizers. The Administrative Amendment, provided as **Appendix A**, was approved on February 25, 2019.

Compliance determination requirements within the FESOP does not require regulatory compliance testing of the dry bed units (FESOP Section D.1.5). There are currently no regulatory requirements within Cook's FESOP governing the performance testing described herein.

PERFORMANCE TEST RESULTS SUMMARY

Sterilizer S8/S9 Chamber Exhaust Vents (Back Vents):

Test Description	Performance Control Efficiency	Target
Performance Demonstration 1 - (Sterilizer 9 Only)	99.9964%	99.00%
Performance Demonstration 2 - (Sterilizer 8 Only)	99.9963%	
AVERAGE	**99.9964%**	

2.0 BACKGROUND

2.1 REGULATORY BACKGROUND

Cook, Incorporated (Cook) operates a stationary medical device manufacturing and sterilization facility located at 6300 North Matthews Drive in Ellettsville, Indiana. EtO is used at this facility to sterilize medical devices that are manufactured both on-site and by a local affiliate. The facility operates in accordance with a Federally Enforceable State Operating Permit (FESOP) issued by the Indiana Department of Environmental Management (No. F105-8436-00030) issued on February 16, 1998.

The facility is required to comply with 40 CFR Part 63, Subpart O, National Emissions Standards for Hazardous Air Pollutants (NESHAP) for Commercial Ethylene Oxide Sterilization Operations. In accordance with the FESOP and NESHAP requirements, Cook conducted an initial performance test of the emissions control system on June 4, 1999. The results of this test established that the performance standards specified in the permit and applicable requirements of the NESHAP were being satisfied. As a condition of this operating permit, Cook is required to reduce Chamber Exhaust Vent (CEV) emissions for Sterilizers S1-S7 by 99%.

A Significant Permit Revision to Cook's Federally Enforceable State Operating Permit (FESOP) Renewal No. F 105-27381-00030, issued on September 7, 2012, allowed Cook to expand sterilizer operations to include two new chambers, Sterilizer's S-8 and S-9. This significant revision approved by IDEM did not require the back-vent emissions from these two sterilizers to be routed through emissions control equipment.

Cook voluntarily submitted and was granted an Administrative Amendment to their Federally Enforceable State Operating Permit (FESOP) Renewal on February 25, 2019 for the installation and operation of back vent controls for Sterilizers S8 and S9. The control equipment, detailed further in Section 2.2, was installed in March 2019 and incorporates the use of three DR490 dry bed reactors run in parallel. Use of the new emissions reduction equipment began in May 2019.

2.1.1 Facility Regulatory Compliance Requirements

A condition of Section D.1.5 of the Second Significant Permit Revision issued by IDEM is that Cook Medical perform performance testing at least once every five (5) years from the date of the most recent compliance demonstration for select equipment. Section D.1.5. of the permit revision imposes performance test requirements on the following control devices:

I. The primary wet acid scrubber, exhausting to stack PS01, controlling EtO emissions from the nine sterilization chambers (S1 through S9.)

II. The one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), exhausting to stack HV01, controlling EtO emissions from the fourteen (14) aeration rooms.

The Cook Ellettsville FESOP does not require periodic compliance testing for any of the Dry Bed units associated with facility back vent emissions control for S1 through S9. Accordingly, there are currently no regulatory requirements within Cook's FESOP governing the testing described herein.

2.2 RELEVANT STERILIZATION OPERATIONS

Cook is currently permitted to operate nine (9) sterilization chambers, however, only chambers S8 and S9 are relevant to the Administrative Amendment and this Performance Test Report. The sterilizers are designed to operate independently in a batch mode. The sterilizer chamber sizes are shown in the following table:

Table 1

Existing Sterilizers and Specifications

Chamber Number	Internal Volume (ft^3)	Capacity (# of pallets)	Current Status
8	[redacted]	[redacted]	Operational
9	[redacted]	[redacted]	Operational

Prior to entering into the back-vent cycle, EtO is evacuated from the sterilization chamber at a nominal flow rate of [redacted] by a dedicated, rotary cam nitrogen sealed dry vacuum pump. This evacuation, typically referred to as the *Sterilization Chamber Vent* cycle, is synonymous with *Sterilant Removal Phase* and lasts approximately [redacted].

After completion of the Sterilant Removal Phase, [redacted] as shown in the diagram below:

[redacted]

2.3 EMISSIONS CONTROL SYSTEMS

Cooks emission reduction systems utilizes a combination of wet-acid scrubbing and chemisorption (dry bed reaction) to control EtO emissions from nine (9) sterilizers and fourteen (14) aeration rooms (hot cells).

The emission control system at Cook's Sterilization Facility consists of two (2) wet acid scrubbers and seven (7) dry bed reactors, as shown within Cook's Emissions Process Flow Diagram provided as **Figure 1** attached to this report. Advanced Air Technologies, Inc. of Corunna, MI manufactured all of the control equipment. The wet-acid scrubbers are model ***Safe Cell II*** and the dry bed reactors model ***DR-490A*** with a rated capacity of [redacted] Only the three dry bed reactors (chemisorbers) associated with Chamber S8 and S9 are relevant to this performance test.

Dry bed reactors remove EtO from gas streams via a gas phase chemical reaction with a granular solid. The solid medium is a proprietary copolymer of styrene and divinylbenzene in the form of small beads. EtO gas molecules contact the porous solid and react with active sites distributed throughout the solid matrix. The small size of the particles increases the surface area to volume ratio of the solid and enhances diffusion of gas through and contact with active sites in the porous matrix. The reaction product is an extended solid with EtO that is chemically bound to the solid medium.

3.0 EMISSIONS CONTROL PERFORMANCE TESTING

3.1 PERFORMANCE TEST

On May 20, 2019, performance testing was conducted by Atlantic and ECSi, Inc in accordance with the Performance Test Protocol prepared by Atlantic and accepted by Cook, Inc. on May 16, 2019. The Test Protocol contains proprietary testing information and can be provided with appropriate redactions upon request.

This Performance Test is being conducted voluntarily to demonstrate that the new emissions reduction systems for the Sterilizer S8 and S9 chamber exhaust vents are performing as designed. The purpose is to determine the reduction efficiency of the three non-regenerable DR-490 dry bed units associated with the back-vent cycles for Sterilizers S8 and S9. The exhaust vent blower installed at Stack SV02 (See **Figure 1**) has [redacted] and matches the combined rating for the three dry bed units in parallel [redacted] Accordingly, evacuations of the back vents completed during the Performance Test were completed individually as the two sterilizers are not allowed to operate simultaneously in the back-vent exhaust phase at the facility.

Sterilization cycles were scheduled to be completed under normal operating conditions, e.g., temperature and pressure, by charging the chambers with EtO at [redacted] Locations of the above-mentioned equipment are shown in **Figure 2** attached to this report.

3.1.1 Performance Demonstration 1: Chamber 9 Back Vents

The first Performance Test was completed for Chamber S9 on May 20, 2019 after the chamber doors were opened to initiate the back-vent Cycle. Sample collection began at 2:09PM and continued for thirteen (13) minutes until the back-vent cycle was complete. Ten (10) samples were collected simultaneously on approximately 1-minute intervals at both the Chamber Back Vent and Dry Bed Outlet. Although flow is not necessary to determine control efficiency during dry bed testing, a flow meter was used to measure velocity within the duct outlet of the dry bed throughout the back-vent cycle. [redacted] and flow readings are shown within **Exhibit A** attached.

Results from Performance Demonstration 1 are provided in Section 6.0 and supporting chromatograms are provided in **Appendix C**.

3.1.2 Performance Demonstration 2: Chamber 8 Back Vents

The second Performance Test was completed for Chamber S8 on May 20, 2019. Sample collection began at 2:38PM and continued for fifteen (15) minutes until the back-vent cycle was complete. Eleven (11) samples were collected simultaneously on approximately 1-minute intervals at both the chamber back vent and dry bed outlet. Although flow is not necessary to determine control efficiency during dry bed testing, a flow meter was used to measure velocity within the duct outlet of the dry bed throughout the back-vent cycle.

Results from Performance Demonstration 2 are provided in Section 6.0 and supporting chromatograms are provided in **Appendix C**. Sample locations are depicted in **Figure 2** and sampling photographs located in **Appendix D.**

3.2 PERFORMANCE TEST METHODS

Performance testing of the dry bed units was completed in accordance with Cook's internal Performance Test Protocol. The performance test results were compared with the minimum performance requirements of the relevant equipment installed.

The testing procedures were established using the United States Environmental Protection Agency (EPA) Method 18: Measurement of Gaseous Organic Compound Emissions by Gas Chromatography). It should be noted that 40 CFR Part 63, Subpart O, does not outline test methods and procedures for Chamber Exhaust Vents. Accordingly, relevant methods from within the California Environmental Protection Agency Air Resources Board (CARB) Method 431 were implemented.

CARB Method 431, Appendix A, specifies that efficiency calculations can be based solely on EtO concentration measurements without volumetric flow measurement as long as the following criteria are met:

I. There is no dilution between the inlet and outlet sampling locations
II. There is identical flow at the inlet and outlet sampling locations, and
III. There is constant flow throughout the duration of the compliance test.

These conditions were all met during the testing performed on May 20, 2019. The performance efficiency of the dry bed units was determined using the average efficiency of a single back-vent cycle for Chamber S8 and a single back-vent cycle for Chamber S9. Refer to Section 3.2.3 for calibration procedures.

3.2.1 EtO Concentration Measurements

EtO mass-mass control efficiency and mass emissions tests were conducted in general accordance with EPA Method 18, § 8.2.2, *Direct Interface Sampling and Analysis Procedure* and CARB Method 431. A gas chromatograph was used on site to simultaneously monitor the EtO concentration in the source gases upstream and downstream of the emission control device.

3.2.2 Gas Chromatograph

EtO samples were analyzed by an SRI, Model 8610C, portable gas chromatograph (GC), with the following applications: programmable column oven temperature from ambient to 400°C, mount up to six detectors and five injectors, control of up to 16 heated zones, three gas sampling valves, and seven EPC gas pressures. Up to six (6) detectors, from a choice of sixteen (16), can be mounted simultaneously. The airbath oven can hold a standard 7-inch diameter megabore column cage, or multiple columns with smaller coil sizes. A flame ionization detector (FID) was used to quantify high-level EtO emissions, and a photoionization detector (PID) was used to quantify low-level EtO emissions at the emission-control device outlet.

Source gas samples were injected into a Gas Chromatograph (GC) equipped with a sampling loop containing a volume of approximately 2cc and maintained at 100°C.

3.2.3 GC Calibration Standards

The FID was calibrated for mid-range part-per-million-by-volume (ppmv) level analyses using gas proportions similar to the following:

1) 1,000 ppmv EtO, balance nitrogen
2) 50 ppmv EtO, balance nitrogen (audit gas)
3) 5 ppmv EtO, balance nitrogen

The PID was calibrated for low-range ppmv level analyses using gas proportions similar to the following

1) 50 ppmv EtO, balance nitrogen (audit gas)
2) 5 ppmv EtO, balance nitrogen

Each of these calibration standards were in separate, certified manufacturer's cylinder. Calibration standards under Method 18 Section 8.2.2.2 and Section 8.2.1.5.2.1 require that the three-point calibration curve be completed with a variance of no greater than 5%. Copies of the chromatograms and calibration curves are provided in **Appendix B**.

4.0 CONTROL-EFFICIENCY CALCULATIONS

The relative difference between the inlet concentration of EtO detected at the sterilization chamber vent and the outlet concentration, if any, of emissions control device represents the effectiveness of the dry bed units with respect to EtO reduction. Efficiency of the dry bed units was calculated as a percentage using the following formula:

EQUATION 1 $$\boldsymbol{Efficiency}\ (\%) = \frac{\boldsymbol{Inlet\ Concentration - Outlet\ Concentration}}{\boldsymbol{Inlet\ Concentration}}$$

The performance efficiency of the dry bed units was determined using the average efficiencies from thirteen (13) samples collected during Performance Demonstration 1 and fifteen (15) samples collected during Performance Demonstration 2.

5.0 QUALITY ASSURANCE / QUALITY CONTROL

5.1 FIELD TESTING QUALITY ASSURANCE

Before the start of analytical work, a system blank was analyzed to ensure that the sampling system was free of EtO. Air was drawn through the sampling system lines to the GC for analysis. After determining that the sampling system was clean, a sample of source gas was injected into the sampling system and analyzed to determine the concentration of any residual EtO present in the sample.

5.2 TEST REPORT QUALITY ASSURANCE

Before submittal, this test report underwent a tiered review by Atlantic staff. A signed certification attesting to the review is presented at the beginning of the report.

1. An initial review of the report and calculations was performed by the report author / project manager.

2. A second review was performed by a colleague (staff engineer / scientist).

3. A final review was performed by the principal of Atlantic's Division of Air Quality.

6.0 PERFORMANCE TEST RESULTS

The following control efficiencies of the EtO emission control systems for the back-vents Emissions Control System were calculated following Section 4.0 using methods outlined in Section 3.0.

Performance Demonstration 1: Sterilizer S9 Back Vents

Sample Time	PPM Reading within Back Vent Duct	PPM Reading at Dry Bed Outlet	Reduction Efficiency
2:09:08 PM	4,140.56 ppm	ND (0.01ppm)	99.9998%
2:10:23 PM	749.15 ppm	ND (0.01ppm)	99.9987%
2:11:35 PM	452.54 ppm	ND (0.01ppm)	99.9978%
2:12:44 PM	355.09 ppm	ND (0.01ppm)	99.9972%
2:13:58 PM	292.48 ppm	ND (0.01ppm)	99.9966%
2:15:06 PM	253.85 ppm	ND (0.01ppm)	99.9961%
2:16:30 PM	231.99 ppm	ND (0.01ppm)	99.9957%
2:17:42 PM	206.30 ppm	ND (0.01ppm)	99.9952%
2:20:09 PM	173.12 ppm	ND (0.01ppm)	99.9942%
2:22:04 PM	147.52 ppm	ND (0.01ppm)	99.9932%
Average Efficiency			99.9964%

Performance Demonstration 2: Sterilizer S8 Back Vents

Sample Time	PPM Reading within Back Vent Duct	PPM Reading at Dry Bed Outlet	Reduction Efficiency
2:38:41 PM*	11,513.34 ppm	ND (0.01ppm)	99.9999%
2:39:57 PM	2,061.62 ppm	ND (0.01ppm)	99.9995%
2:41:28 PM	544.83 ppm	ND (0.01ppm)	99.9982%
2:42:38 PM	375.36 ppm	ND (0.01ppm)	99.9973%
2:43:58 PM	305.66 ppm	ND (0.01ppm)	99.9967%
2:45:46 PM	250.57 ppm	ND (0.01ppm)	99.9960%
2:47:04 PM	218.33 ppm	ND (0.01ppm)	99.9954%
2:48:37 PM	191.65 ppm	ND (0.01ppm)	99.9948%
2:49:46 PM	172.64 ppm	ND (0.01ppm)	99.9942%
2:51:06 PM	164.47 ppm	ND (0.01ppm)	99.9939%
2:53:03 PM	142.99 ppm	ND (0.01ppm)	99.9930%
Average Efficiency			99.9963%

The average tested control efficiency associated with the dry bed units associated with Chamber S8 and Chamber S9 back vents, installed in March 2019, was demonstrated to be **99.9964%**.

As detailed in Section 3.2.3, a 3-point calibration of the GC was completed by analyzing each gas mixture in triplicate. If another method were to be used other than Method 18, such as an 8-point calibration curve, the detection limit of the on-site GC may increase to 0.1ppm. In the event a 0.1 ppm detection limit were used, the resulting calculated efficiency of the dry bed units would be represented as 99.964%.

FIGURE 1

Confidential Business Information

[redacted]

FIGURE 2

Confidential Business Information

APPENDIX A

ADMINISTRATIVE AMENDMENT

Confidential Business Information

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
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Eric J. Holcomb
Governor

Bruno L. Pigott
Commissioner

SENT VIA U.S. MAIL: CONFIRMED DELIVERY AND SIGNATURE REQUESTED

TO: Shawn Adams
COOK INCORPORATED
PO Box 489
Bloomington, IN 47402

DATE: February 25, 2019

FROM: Jenny Acker, Branch Chief
Permits Branch
Office of Air Quality

SUBJECT: Final Decision
FESOP Administrative Amendment
105-41050-00030

Enclosed is the final decision and supporting materials for the air permit application referenced above. Please note that this packet contains the original, signed, permit documents.

The final decision is being sent to you because our records indicate that you are the contact person for this application. However, if you are not the appropriate person within your company to receive this document, please forward it to the correct person.

A copy of the final decision and supporting materials has also been sent via standard mail to:
Derek Voskuil COOK INCORPORATED PO Box 489 Bloomington IN
Simon Thomas Atlantic Design Engineers

In addition, the Notice of Decision has been sent to the OAQ Permits Branch Interested Parties List.

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178, or toll-free at 1-800-451-6027 (ext. 3-0178), and ask to speak to the permit reviewer who prepared the permit. If you think you have received this document in error, please contact Joanne Smiddie-Brush of my staff at 1-800-451-6027 (ext 3-0185), or via e-mail at jbrush@idem.IN.gov.

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Eric J. Holcomb
Governor

Bruno L. Pigott
Commissioner

To: Interested Parties

Date: February 25, 2019

From: Jenny Acker, Chief
Permits Branch
Office of Air Quality

Source Name: Cook Inc.

Permit Level: FESOP Administrative Amendment

Permit Number: 105-41050-00030

Source Location: 6330 North Matthews Drive, Ellettsville, Indiana

Type of Action Taken: Changes that are administrative in nature

Notice of Decision: Approval

Please be advised that on behalf of the Commissioner of the Department of Environmental Management, I have issued a decision regarding the matter referenced above. Pursuant to 326 IAC 2, this approval was effective immediately upon submittal of the application.

The final decision is available on the IDEM website at: http://www.in.gov/apps/idem/caats/
To view the document, choose Search Option **by Permit Number**, then enter permit 41050.

The final decision is also available via IDEM's Virtual File Cabinet (VFC). Please go to: http://www.IN.idem/gov and enter VFC in the search box. You will then have the option to search for permit documents using a variety of criteria.

(continues on next page)

If you would like to request a paper copy of the permit document, please contact IDEM's IDEM's Office of Records Management:

IDEM - Office of Records Management
Indiana Government Center North, Room 1207
100 North Senate Avenue
Indianapolis, IN 46204
Phone: (317) 232-8667
Fax: (317) 233-6647
Email: IDEMFILEROOM@idem.in.gov

If you wish to challenge this decision, IC 4-21.5-3-7 requires that you file a petition for administrative review. This petition may include a request for stay of effectiveness and must be submitted to the Office of Environmental Adjudication, 100 North Senate Avenue, Government Center North, Room N103, Indianapolis, IN 46204, **within eighteen (18) calendar days from the mailing of this notice**. The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:

(1) the date the document is delivered to the Office of Environmental Adjudication (OEA);
(2) the date of the postmark on the envelope containing the document, if the document is mailed to OEA by U.S. mail; or
(3) The date on which the document is deposited with a private carrier, as shown by receipt issued by the carrier, if the document is sent to the OEA by private carrier.

The petition must include facts demonstrating that you are either the applicant, a person aggrieved or adversely affected by the decision or otherwise entitled to review by law. Please identify the permit, decision, or other order for which you seek review by permit number, name of the applicant, location, date of this notice and all of the following:

(1) the name and address of the person making the request;
(2) the interest of the person making the request;
(3) identification of any persons represented by the person making the request;
(4) the reasons, with particularity, for the request;
(5) the issues, with particularity, proposed for considerations at any hearing; and
(6) identification of the terms and conditions which, in the judgment of the person making the request, would be appropriate in the case in question to satisfy the requirements of the law governing documents of the type issued by the Commissioner.

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178. Callers from within Indiana may call toll-free at 1-800-451-6027, ext. 3-0178.

Enclosures
Decision Permit Amdendment 9/27/17

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Eric J. Holcomb
Governor

Bruno L. Pigott
Commissioner

February 25, 2019

Mr. Shawn Adams
Cook Incorporated
P.O. Box 489
Bloomington, IN 47402-0489

Re: 105-41050-00030
Administrative Amendment to
FESOP Renewal No. 105-27381-00030

Dear Adams:

Cook Incorporated was issued a Federally Enforceable State Operating Permit (FESOP) Renewal No. 105-27381-00030 on August 24, 2009 for a stationary medical device manufacturing and sterilization operation located at 6300 North Matthews Drive, Ellettsville, IN 47429. On January 2, 2019, the Office of Air Quality (OAQ) received an application from the source requesting to add voluntary emissions control equipment.

Pursuant to the provisions of 326 IAC 2-8-10(a), the permit is hereby administratively amended as described in the attached Technical Support Document.

All other conditions of the permit shall remain unchanged and in effect. Please find attached the entire FESOP as amended. The permit references the below listed attachment(s).

Attachment A:	40 CFR 63, Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities
Attachment B:	40 CFR 63, Subpart ZZZZ, Stationary Reciprocating Internal Combustion Engines

Previously issued approvals for this source containing these attachments are available on the Internet at: http://www.in.gov/ai/appfiles/idem-caats/.

Previously issued approvals for this source are also available via IDEM's Virtual File Cabinet (VFC). Please go to: http://www.in.gov/idem/ and enter VFC in the search box. You will then have the option to search for permit documents using a variety of criteria.

Federal rules under Title 40 of United States Code of Federal Regulations may also be found on the U.S. Government Printing Office's Electronic Code of Federal Regulations (eCFR) website, located on the Internet at: http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title40/40tab_02.tpl.

A copy of the permit is available on the Internet at: http://www.in.gov/ai/appfiles/idem-caats/. A copy of the permit is also available via IDEM's Virtual File Cabinet (VFC). Please go to: http://www.in.gov/idem/ and enter VFC in the search box. You will then have the option to search for permit documents using a variety of criteria. For additional information about air permits and how the public and interested parties can participate, refer to the IDEM Air Permits page on the Internet at: http://www.in.gov/idem/airquality/2356.htm; and the Citizens' Guide to IDEM on the Internet at: http://www.in.gov/idem/6900.htm.

This decision is subject to the Indiana Administrative Orders and Procedures Act - IC 4-21.5-3-5.

If you have any questions regarding this matter, please contact Tamara Havics, Indiana Department Environmental Management, Office of Air Quality, Permits Branch, 100 North Senate Avenue, MC 61-53 IGCN 1003, Indianapolis, Indiana 46204-2251, or by telephone at (317) 232-8219 or (800) 451-6027, and ask for Tamara Havics or (317) 232-8219.

Sincerely,

Tripurari P. Sinha, Ph.D., Section Chief
Permits Branch
Office of Air Quality

Attachment(s): Updated Permit and Technical Support Document

cc: File - Monroe County
Monroe County Health Department
U.S. EPA, Region 5
Compliance and Enforcement Branch
IDEM Southeast Regional Office

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Eric J. Holcomb
Governor

Bruno L. Pigott
Commissioner

Federally Enforceable State Operating Permit Renewal
OFFICE OF AIR QUALITY

Cook Incorporated
6330 North Matthews Drive
Ellettsville, Indiana 47429

(herein known as the Permittee) is hereby authorized to operate subject to the conditions contained herein, the source described in Section A (Source Summary) of this permit.

The Permittee must comply with all conditions of this permit. Noncompliance with any provisions of this permit is grounds for enforcement action; permit termination, revocation and reissuance, or modification; or denial of a permit renewal application. It shall not be a defense for the Permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit. An emergency does constitute an affirmative defense in an enforcement action provided the Permittee complies with the applicable requirements set forth in Section B, Emergency Provisions.

This permit is issued in accordance with 326 IAC 2 and 40 CFR Part 70 Appendix A and contains the conditions and provisions specified in 326 IAC 2-8 as required by 42 U.S.C. 7401, et. seq. (Clean Air Act as amended by the 1990 Clean Air Act Amendments), 40 CFR Part 70.6, IC 13-15 and IC 13-17.

Indiana statutes from IC 13 and rules from 326 IAC, quoted in conditions in this permit, are those applicable at the time the permit was issued. The issuance or possession of this permit shall not alone constitute a defense against an alleged violation of any law, regulation or standard, except for the requirement to obtain a FESOP under 326 IAC 2-8.

Operation Permit No.: F105-27381-00030 Master Agency Interest ID: 11774	
Issued by/Original Signed by: Alfred C. Dumaual, Ph. D., Section Chief Permits Branch Office of Air Quality	Issuance Date: August 24, 2009 Expiration Date: August 24, 2019

First Significant Permit Revision No.: 105-29042-00030, issued June 25, 2010
Interim Significant Permit Revision No.: 105-32055i-00030, issued July 25, 2012
Second Significant Permit Revision No.: F105-32055-00030, issued September 7, 2012

Administrative Amendment No.: 105-41050-00030	
Issued by: Tripurari Sinha Tripurari P. Sinha, Ph.D., Section Chief Permits Branch Office of Air Quality	Issuance Date: February 25, 2019 Expiration Date: August 24, 2019

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SECTION A SOURCE SUMMARY

This permit is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ). The information describing the source contained in conditions A.1 through A.3 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this permit pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

A.1 General Information [326 IAC 2-8-3(b)]

The Permittee owns and operates a stationary medical device manufacturing and sterilization operation.

Source Address:	6330 North Matthews Drive, Ellettsville, Indiana 47429
General Source Phone Number:	(800) 468-1379
SIC Code:	3841(Surgical and Medical Instruments and Apparatus)
County Location:	Monroe
Source Location Status:	Attainment for all criteria pollutants
Source Status:	Federally Enforceable State Operating Permit Program Minor Source, under PSD and Emission Offset Rules Minor Source, Section 112 of the Clean Air Act Not 1 of 28 Source Categories

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-8-3(c)(3)]

This stationary source consists of the following emission units and pollution control devices:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and with chamber exhaust vents (back vents) exhausting to one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01. Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004;

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02;

(c) Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, of which zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01; and

Under 40 CFR 63, Subpart O, emission units (a), (b), and (c) listed above are considered affected facilities. [40 CFR 63, Subpart O][326 IAC 20-5]

(d) Miscellaneous cleaning with isopropyl alcohol (IPA).

(e) One (1) diesel-fired emergency generator, identified as Unit #1, installed on July 31, 2003 and approved for construction in 2010, with a maximum capacity of 1850 hp, with emissions uncontrolled, and exhausting to the atmosphere.

This unit is considered an existing affected facility under 40 CFR 63, Subpart ZZZZ.

(f) One (1) diesel-fired emergency generator, identified as Unit #2, installed on November 19, 2003 and approved for construction in 2010, with a maximum capacity of 2922 hp, with emissions uncontrolled, and exhausting to the atmosphere.

This unit is considered an existing affected facility under 40 CFR 63, Subpart ZZZZ.

A.3 Insignificant Activities [326 IAC 2-7-1(21)][326 IAC 2-8-3(c)(3)(I)]

This stationary source also includes the following insignificant activities:

(a) One (1) manual plastic tubing and metal wiring slip coating operation, consisting of five trays using a maximum total of 0.033 gallons of coating per hour, exhausting through one (1) stack, identified as E07;

(b) The following storage containers:

(1) nine (9) 100% ethylene oxide storage cylinders with a maximum storage capacity of 400 pounds of ethylene oxide each (3,600 pounds total). These are portable cylinders that will be connected to the sterilization process;

(2) nine (9) 100% ethylene oxide storage cylinders each with a maximum storage capacity of 400 pounds of ethylene oxide on standby for connection to the sterilization process as cylinders are emptied;

(3) up to four (4) additional 100% ethylene oxide storage cylinders each with a maximum storage capacity of 400 pounds of ethylene oxide to be stored on site;

(c) Three (3) liquor storage tanks, identified as Tanks A, B, and C, each with a working storage capacity of 5,870 gallons, all venting to the wet acid pre-scrubber, exhausting through one (1) stack, identified as HV01;

(d) Gluing, heat forming, tapering, marking and printing operations associated with manufacturing activities and product assembly, exhausting through building exhausts and one (1) stack, identified as S10;

(e) Natural gas fired combustion sources with a total heat input of 20.45 MMBtu per hour, including the following:

(1) One natural gas-fired boiler, identified as C238-F, constructed in 2000, with a maximum heat input capacity of 0.45 MMBtu per hour;

(2) One natural gas-fired boiler, identified as C240-F, constructed in 2003, with a maximum heat input capacity of 1.26 MMBtu per hour;

(3) One natural gas-fired boiler, identified as C241-F, constructed in 2003, with a maximum heat input capacity of 2.1349 MMBtu per hour;

(4) One natural gas-fired boiler, identified as C242-F, constructed in 2003, with a maximum heat input capacity of 2.1349 MMBtu per hour;

(5) One natural gas-fired boiler, identified as C239-F, constructed in 2004, with a maximum heat input capacity of 1.26 MMBtu per hour;

(6) One natural gas-fired boiler, identified as C246-F, constructed in 2004, with a

maximum heat input capacity of 1.5 MMBtu per hour;

(7) One natural gas-fired boiler, identified as C230-F, constructed in 2006, with a maximum heat input capacity of 1.68 MMBtu per hour;

(8) One natural gas-fired boiler, identified as C231-F, constructed in 2006, with a maximum heat input capacity of 1.68 MMBtu per hour;

(9) One natural gas-fired boiler, identified as C232-F, constructed in 2006, with a maximum heat input capacity of 7.0 MMBtu per hour;

(10) One natural gas-fired boiler, identified as C233-F, constructed in 2006, with a maximum heat input capacity of 0.85 MMBtu per hour;

(11) One natural gas-fired boiler, identified as C364-F, constructed in 2010, with a maximum heat input capacity of 0.5 MMBtu per hour;

(f) Vessels storing lubricating oils, hydraulic oils, machining oils, and machining fluids;

(g) Application of oils, greases, lubricants, or other nonvolatile materials applied as temporary protective coatings;

(h) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment; [326 IAC 6-3-2]

(i) Closed loop heating and cooling systems;

(j) Exposure chambers ("towers", "columns"), for curing of ultra-violet inks and ultra-violet coatings where heat is the intended discharge;

(k) Replacement or repair of electrostatic precipitators, bags in baghouses and filters in other air filtration equipment;

(l) Heat exchanger cleaning and repair;

(m) TDMAC package prep operations, exhausting through one (1) stack, identified as S07;

(n) Heat forming, taping, masking, and printing operations exhausting through various building exhausts;

(o) Catheter Impregnation Process consisting of the following:

(1) A total of six (6) immersion tanks in one (1) immersion booth, with two (2) wells per tank for a total of twelve (12) wells, each well with a capacity of 2880 cubic inches per tank and a weekly usage six (6) liters of solvent and antibiotic solution;

(2) A total of four (4) silicon or polyurethane tubes drying booths; and

(3) A total of one (1) formulation booth, where the immersion solution is mixed.

with potential single HAP (Methanol) emissions of 0.12 tons per year and potential VOC emission of 0.90 tons per year; and

(p) Paclitaxel Treatment Process consisting of the following:

(1) One (1) raw materials mix hood; and

(2) Two (2) Paclitaxel treatment booths.

with potential VOC emissions of less than 15 pounds per day for each booth.

A.4 FESOP Applicability [326 IAC 2-8-2]

This stationary source, otherwise required to have a Part 70 permit as described in 326 IAC 2-7-2(a), has applied to the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ) to renew a Federally Enforceable State Operating Permit (FESOP).

SECTION B GENERAL CONDITIONS

B.1 Definitions [326 IAC 2-8-1]

Terms in this permit shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, the applicable definitions found in the statutes or regulations (IC 13-11, 326 IAC 1-2 and 326 IAC 2-7) shall prevail.

B.2 Permit Term [326 IAC 2-8-4(2)][326 IAC 2-1.1-9.5][IC 13-15-3-6(a)]

(a) This permit, F105-27381-000030, is issued for a fixed term of ten (10) years from the issuance date of this permit, as determined in accordance with IC 4-21.5-3-5(f) and IC 13-15-5-3. Subsequent revisions, modifications, or amendments of this permit do not affect the expiration date of this permit.

(b) If IDEM, OAQ, upon receiving a timely and complete renewal permit application, fails to issue or deny the permit renewal prior to the expiration date of this permit, this existing permit shall not expire and all terms and conditions shall continue in effect, until the renewal permit has been issued or denied.

B.3 Term of Conditions [326 IAC 2-1.1-9.5]

Notwithstanding the permit term of a permit to construct, a permit to operate, or a permit modification, any condition established in a permit issued pursuant to a permitting program approved in the state implementation plan shall remain in effect until:

(a) the condition is modified in a subsequent permit action pursuant to Title I of the Clean Air Act; or

(b) the emission unit to which the condition pertains permanently ceases operation.

B.4 Enforceability [326 IAC 2-8-6][IC 13-17-12]

Unless otherwise stated, all terms and conditions in this permit, including any provisions designed to limit the source's potential to emit, are enforceable by IDEM, the United States Environmental Protection Agency (U.S. EPA) and by citizens in accordance with the Clean Air Act.

B.5 Severability [326 IAC 2-8-4(4)]

The provisions of this permit are severable; a determination that any portion of this permit is invalid shall not affect the validity of the remainder of the permit.

B.6 Property Rights or Exclusive Privilege [326 IAC 2-8-4(5)(D)]

This permit does not convey any property rights of any sort or any exclusive privilege.

B.7 Duty to Provide Information [326 IAC 2-8-4(5)(E)]

(a) The Permittee shall furnish to IDEM, OAQ, within a reasonable time, any information that IDEM, OAQ may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with this permit. Upon request, the Permittee shall also furnish to IDEM, OAQ copies of records required to be kept by this permit.

(b) For information furnished by the Permittee to IDEM, OAQ, the Permittee may include a claim of confidentiality in accordance with 326 IAC 17.1. When furnishing copies of requested records directly to U. S. EPA, the Permittee may assert a claim of confidentiality in accordance with 40 CFR 2, Subpart B.

B.8 Certification [326 IAC 2-8-3(d)][326 IAC 2-8-4(3)(C)(i)][326 IAC 2-8-5(1)]

(a) A certification required by this permit meets the requirements of 326 IAC 2-8-5(a)(1) if:

(1) it contains a certification by an "authorized individual", as defined by 326 IAC 2-1.1-1(1), and

(2) the certification states that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

(b) The Permittee may use the attached Certification Form, or its equivalent with each submittal requiring certification. One (1) certification may cover multiple forms in one (1) submittal.

(c) An "authorized individual" is defined at 326 IAC 2-1.1-1(1).

B.9 Annual Compliance Certification [326 IAC 2-8-5(a)(1)]

(a) The Permittee shall annually submit a compliance certification report which addresses the status of the source's compliance with the terms and conditions contained in this permit, including emission limitations, standards, or work practices. All certifications shall cover the time period from January 1 to December 31 of the previous year, and shall be submitted no later than July 1 of each year to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

(b) The annual compliance certification report required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ on or before the date it is due.

(c) The annual compliance certification report shall include the following:

(1) The appropriate identification of each term or condition of this permit that is the basis of the certification;

(2) The compliance status;

(3) Whether compliance was continuous or intermittent;

(4) The methods used for determining the compliance status of the source, currently and over the reporting period consistent with 326 IAC 2-8-4(3); and

(5) Such other facts, as specified in Sections D of this permit, as IDEM, OAQ may require to determine the compliance status of the source.

The submittal by the Permittee does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

B.10 Compliance Order Issuance [326 IAC 2-8-5(b)]

IDEM, OAQ may issue a compliance order to this Permittee upon discovery that this permit is in nonconformance with an applicable requirement. The order may require immediate compliance or contain a schedule for expeditious compliance with the applicable requirement.

B.11 Preventive Maintenance Plan [326 IAC 1-6-3][326 IAC 2-8-4(9)]

(a) A Preventive Maintenance Plan meets the requirements of 326 IAC 1-6-3 if it includes, at a minimum:

(1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;

(2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and

(3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

The Permittee shall implement the PMPs.

(b) If required by specific condition(s) in Section D of this permit where no PMP was previously required, the Permittee shall prepare and maintain Preventive Maintenance Plans (PMPs) no later than ninety (90) days after issuance of this permit or ninety (90) days after initial start-up, whichever is later, including the following information on each facility:

(1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;

(2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and

(3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

If, due to circumstances beyond the Permittee's control, the PMPs cannot be prepared and maintained within the above time frame, the Permittee may extend the date an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

The PMP extension notification does not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

The Permittee shall implement the PMPs.

(c) A copy of the PMPs shall be submitted to IDEM, OAQ upon request and within a reasonable time, and shall be subject to review and approval by IDEM, OAQ. IDEM, OAQ may require the Permittee to revise its PMPs whenever lack of proper maintenance causes or is the primary contributor to an exceedance of any limitation on emissions. The PMPs and their submittal do not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(d) To the extent the Permittee is required by 40 CFR Part 60/63 to have an Operation Maintenance, and Monitoring (OMM) Plan for a unit, such Plan is deemed to satisfy the PMP requirements of 326 IAC 1-6-3 for that unit.

B.12 Emergency Provisions [326 IAC 2-8-12]

(a) An emergency, as defined in 326 IAC 2-7-1(12), is not an affirmative defense for an action brought for noncompliance with a federal or state health-based emission limitation except as provided in 326 IAC 2-8-12.

(b) An emergency, as defined in 326 IAC 2-7-1(12), constitutes an affirmative defense to an action brought for noncompliance with a health-based or technology-based emission limitation if the affirmative defense of an emergency is demonstrated through properly signed, contemporaneous operating logs or other relevant evidence that describe the following:

(1) An emergency occurred and the Permittee can, to the extent possible, identify the causes of the emergency;

(2) The permitted facility was at the time being properly operated;

(3) During the period of an emergency, the Permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards or other requirements in this permit;

(4) For each emergency lasting one (1) hour or more, the Permittee notified IDEM, OAQ, or Southeast Regional Office within four (4) daytime business hours after the beginning of the emergency, or after the emergency was discovered or reasonably should have been discovered;

Telephone Number: 1-800-451-6027 (ask for Office of Air Quality, Compliance and Enforcement Branch), or
Telephone Number: 317-233-0178 (ask for Office of Air Quality, Compliance and Enforcement Branch)
Facsimile Number: 317-233-6865
Southeast Regional Office phone: (812) 358-2027; fax: (812) 358-2058.

(5) For each emergency lasting one (1) hour or more, the Permittee submitted the attached Emergency Occurrence Report Form or its equivalent, either by mail or facsimile to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

within two (2) working days of the time when emission limitations were exceeded due to the emergency.

The notice fulfills the requirement of 326 IAC 2-8-4(3)(C)(ii) and must contain the following:

(A) A description of the emergency;

(B) Any steps taken to mitigate the emissions; and

(C) Corrective actions taken.

The notification which shall be submitted by the Permittee does not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(6) The Permittee immediately took all reasonable steps to correct the emergency.

(c) In any enforcement proceeding, the Permittee seeking to establish the occurrence of an emergency has the burden of proof.

(d) This emergency provision supersedes 326 IAC 1-6 (Malfunctions). This permit condition is in addition to any emergency or upset provision contained in any applicable requirement.

(e) The Permittee seeking to establish the occurrence of an emergency shall make records available upon request to ensure that failure to implement a PMP did not cause or contribute to an exceedance of any limitations on emissions. However, IDEM, OAQ may require that the Preventive Maintenance Plans required under 326 IAC 2-8-3(c)(6) be revised in response to an emergency.

(f) Failure to notify IDEM, OAQ by telephone or facsimile of an emergency lasting more than one (1) hour in accordance with (b)(4) and (5) of this condition shall constitute a violation of 326 IAC 2-8 and any other applicable rules.

(g) Operations may continue during an emergency only if the following conditions are met:

(1) If the emergency situation causes a deviation from a technology-based limit, the Permittee may continue to operate the affected emitting facilities during the emergency provided the Permittee immediately takes all reasonable steps to correct the emergency and minimize emissions.

(2) If an emergency situation causes a deviation from a health-based limit, the Permittee may not continue to operate the affected emissions facilities unless:

(A) The Permittee immediately takes all reasonable steps to correct the emergency situation and to minimize emissions; and

(B) Continued operation of the facilities is necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw material of substantial economic value.

Any operations shall continue no longer than the minimum time required to prevent the situations identified in (g)(2)(B) of this condition.

B.13 Prior Permits Superseded [326 IAC 2-1.1-9.5]

(a) All terms and conditions of permits established prior to F105-27381-000030 and issued pursuant to permitting programs approved into the state implementation plan have been either:

(1) incorporated as originally stated,

(2) revised, or

(3) deleted.

(b) All previous registrations and permits are superseded by this permit.

B.14 Termination of Right to Operate [326 IAC 2-8-9][326 IAC 2-8-3(h)]

The Permittee's right to operate this source terminates with the expiration of this permit unless a timely and complete renewal application is submitted at least nine (9) months prior to the date of expiration of the source's existing permit, consistent with 326 IAC 2-8-3(h) and 326 IAC 2-8-9.

B.15 Permit Modification, Reopening, Revocation and Reissuance, or Termination [326 IAC 2-8-4(5)(C)][326 IAC 2-8-7(a)][326 IAC 2-8-8]

(a) This permit may be modified, reopened, revoked and reissued, or terminated for cause. The filing of a request by the Permittee for a Federally Enforceable State Operating Permit modification, revocation and reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any condition of this permit. [326 IAC 2-8-4(5)(C)] The notification by the Permittee does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(b) This permit shall be reopened and revised under any of the circumstances listed in IC 13-15-7-2 or if IDEM, OAQ determines any of the following:

(1) That this permit contains a material mistake.

(2) That inaccurate statements were made in establishing the emissions standards or other terms or conditions.

(3) That this permit must be revised or revoked to assure compliance with an applicable requirement. [326 IAC 2-8-8(a)]

(c) Proceedings by IDEM, OAQ to reopen and revise this permit shall follow the same procedures as apply to initial permit issuance and shall affect only those parts of this permit for which cause to reopen exists. Such reopening and revision shall be made as expeditiously as practicable. [326 IAC 2-8-8(b)]

(d) The reopening and revision of this permit, under 326 IAC 2-8-8(a), shall not be initiated before notice of such intent is provided to the Permittee by IDEM, OAQ at least thirty (30) days in advance of the date this permit is to be reopened, except that IDEM, OAQ may provide a shorter time period in the case of an emergency. [326 IAC 2-8-8(c)]

B.16 Permit Renewal [326 IAC 2-8-3(h)]

(a) The application for renewal shall be submitted using the application form or forms prescribed by IDEM, OAQ and shall include the information specified in 326 IAC 2-8-3. Such information shall be included in the application for each emission unit at this source, except those emission units included on the trivial or insignificant activities list contained in 326 IAC 2-7-1(21) and 326 IAC 2-7-1(40). The renewal application does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

Request for renewal shall be submitted to:

Indiana Department of Environmental Management
Permit Administration and Support Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

(b) A timely renewal application is one that is:

(1) Submitted at least nine (9) months prior to the date of the expiration of this permit; and

(2) If the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ on or before the date it is due.

(c) If the Permittee submits a timely and complete application for renewal of this permit, the source's failure to have a permit is not a violation of 326 IAC 2-8 until IDEM, OAQ takes final action on the renewal application, except that this protection shall cease to apply if, subsequent to the completeness determination, the Permittee fails to submit by the deadline specified, pursuant to 326 IAC 2-8-3(g), in writing by IDEM, OAQ any additional information identified as being needed to process the application.

B.17 Permit Amendment or Revision [326 IAC 2-8-10][326 IAC 2-8-11.1]

(a) Permit amendments and revisions are governed by the requirements of 326 IAC 2-8-10 or 326 IAC 2-8-11.1 whenever the Permittee seeks to amend or modify this permit.

(b) Any application requesting an amendment or modification of this permit shall be submitted to:

Indiana Department of Environmental Management
Permit Administration and Support Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

Any such application does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-8-10(b)(3)]

B.18 Operational Flexibility [326 IAC 2-8-15][326 IAC 2-8-11.1]

(a) The Permittee may make any change or changes at the source that are described in 326 IAC 2-8-15(b) and (c) without a prior permit revision, if each of the following conditions is met:

(1) The changes are not modifications under any provision of Title I of the Clean Air Act;

(2) Any approval required by 326 IAC 2-8-11.1 has been obtained;

(3) The changes do not result in emissions which exceed the limitations provided in this permit (whether expressed herein as a rate of emissions or in terms of total emissions);

(4) The Permittee notifies the:

Indiana Department of Environmental Management
Permit Administration and Support Section, Office of Air Quality
100 North Senate Avenue

MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

and

United States Environmental Protection Agency, Region V
Air and Radiation Division, Regulation Development Branch - Indiana (AR-18J)
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

in advance of the change by written notification at least ten (10) days in advance of the proposed change. The Permittee shall attach every such notice to the Permittee's copy of this permit; and

(5) The Permittee maintains records on-site, on a rolling five (5) year basis, which document all such changes and emission trades that are subject to 326 IAC 2-8-15(b)(1) and (c). The Permittee shall make such records available, upon reasonable request, for public review.

Such records shall consist of all information required to be submitted to IDEM, OAQ in the notices specified in 326 IAC 2-8-15(b)(1) and (c).

(b) Emission Trades [326 IAC 2-8-15(b)]
The Permittee may trade emissions increases and decreases at the source, where the applicable SIP provides for such emission trades without requiring a permit revision, subject to the constraints of Section (a) of this condition and those in 326 IAC 2-8-15(c).

(c) Alternative Operating Scenarios [326 IAC 2-8-15(c)]
The Permittee may make changes at the source within the range of alternative operating scenarios that are described in the terms and conditions of this permit in accordance with 326 IAC 2-8-4(7). No prior notification of IDEM, OAQ, or U.S. EPA is required.

(d) Backup fuel switches specifically addressed in, and limited under, Section D of this permit shall not be considered alternative operating scenarios. Therefore, the notification requirements of part (a) of this condition do not apply.

B.19 Source Modification Requirement [326 IAC 2-8-11.1]

A modification, construction, or reconstruction is governed by the requirements of 326 IAC 2.

B.20 Inspection and Entry [326 IAC 2-8-5(a)(2)][IC 13-14-2-2][IC 13-17-3-2][IC 13-30-3-1]

Upon presentation of proper identification cards, credentials, and other documents as may be required by law, and subject to the Permittee's right under all applicable laws and regulations to assert that the information collected by the agency is confidential and entitled to be treated as such, the Permittee shall allow IDEM, OAQ, U.S. EPA, or an authorized representative to perform the following:

(a) Enter upon the Permittee's premises where a FESOP source is located, or emissions related activity is conducted, or where records must be kept under the conditions of this permit;

(b) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;

(c) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, inspect, at reasonable times, any facilities, equipment (including monitoring and air

pollution control equipment), practices, or operations regulated or required under this permit;

(d) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, sample or monitor, at reasonable times, substances or parameters for the purpose of assuring compliance with this permit or applicable requirements; and

(e) As authorized by the Clean Air Act, IC 13-14-2-2, IC 13-17-3-2, and IC 13-30-3-1, utilize any photographic, recording, testing, monitoring, or other equipment for the purpose of assuring compliance with this permit or applicable requirements.

B.21 Transfer of Ownership or Operational Control [326 IAC 2-8-10]

(a) The Permittee must comply with the requirements of 326 IAC 2-8-10 whenever the Permittee seeks to change the ownership or operational control of the source and no other change in the permit is necessary.

(b) Any application requesting a change in the ownership or operational control of the source shall contain a written agreement containing a specific date for transfer of permit responsibility, coverage and liability between the current and new Permittee. The application shall be submitted to:

Indiana Department of Environmental Management
Permit Administration and Support Section, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

Any such application does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-8-10(b)(3)]

B.22 Annual Fee Payment [326 IAC 2-7-19][326 IAC 2-8-4(6)][326 IAC 2-8-16][326 IAC 2-1.1-7]

(a) The Permittee shall pay annual fees to IDEM, OAQ no later than thirty (30) calendar days of receipt of a billing. Pursuant to 326 IAC 2-7-19(b), if the Permittee does not receive a bill from IDEM, OAQ the applicable fee is due April 1 of each year.

(b) Failure to pay may result in administrative enforcement action or revocation of this permit.

(c) The Permittee may call the following telephone numbers: 1-800-451-6027 or 317-233-4230 (ask for OAQ, Billing, Licensing, and Training Section), to determine the appropriate permit fee.

B.23 Credible Evidence [326 IAC 2-8-4(3)][326 IAC 2-8-5][62 FR 8314][326 IAC 1-1-6]

For the purpose of submitting compliance certifications or establishing whether or not the Permittee has violated or is in violation of any condition of this permit, nothing in this permit shall preclude the use, including the exclusive use, of any credible evidence or information relevant to whether the Permittee would have been in compliance with the condition of this permit if the appropriate performance or compliance test or procedure had been performed.

SECTION C **SOURCE OPERATION CONDITIONS**

Entire Source

Emission Limitations and Standards [326 IAC 2-8-4(1)]

C.1 Particulate Emission Limitations For Processes with Process Weight Rates Less Than One Hundred (100) Pounds per Hour [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2(e)(2), particulate emissions from any process not exempt under 326 IAC 6-3-1(b) or (c) which has a maximum process weight rate less than 100 pounds per hour and the methods in 326 IAC 6-3-2(b) through (d) do not apply shall not exceed 0.551 pounds per hour.

C.2 Overall Source Limit [326 IAC 2-8]

The purpose of this permit is to limit this source's potential to emit to less than major source levels for the purpose of Section 502(a) of the Clean Air Act.

(a) Pursuant to 326 IAC 2-8:

(1) The potential to emit any regulated pollutant, except particulate matter (PM) and greenhouse gases (GHGs), from the entire source shall be limited to less than one hundred (100) tons per twelve (12) consecutive month period.

(2) The potential to emit any individual hazardous air pollutant (HAP) from the entire source shall be limited to less than ten (10) tons per twelve (12) consecutive month period; and

(3) The potential to emit any combination of HAPs from the entire source shall be limited to less than twenty-five (25) tons per twelve (12) consecutive month period.

(4) The potential to emit greenhouse gases (GHGs) from the entire source shall be limited to less than one hundred thousand (100,000) tons of CO2 equivalent emissions (CO2e) per twelve (12) consecutive month period.

(b) Pursuant to 326 IAC 2-2 (PSD), potential to emit particulate matter (PM) from the entire source shall be limited to less than two hundred fifty (250) tons per twelve (12) consecutive month period.

(c) This condition shall include all emission points at this source including those that are insignificant as defined in 326 IAC 2-7-1(21). The source shall be allowed to add insignificant activities not already listed in this permit, provided that the source's potential to emit does not exceed the above specified limits.

(d) Section D of this permit contains independently enforceable provisions to satisfy this requirement.

C.3 Opacity [326 IAC 5-1]

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-1 (Applicability) and 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), opacity shall meet the following, unless otherwise stated in this permit:

(a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

(b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

C.4 Open Burning [326 IAC 4-1][IC 13-17-9]

The Permittee shall not open burn any material except as provided in 326 IAC 4-1-3, 326 IAC 4-1-4 or 326 IAC 4-1-6. The previous sentence notwithstanding, the Permittee may open burn in accordance with an open burning approval issued by the Commissioner under 326 IAC 4-1-4.1.

C.5 Incineration [326 IAC 4-2][326 IAC 9-1-2]

The Permittee shall not operate an incinerator except as provided in 326 IAC 4-2 or in this permit. The Permittee shall not operate a refuse incinerator or refuse burning equipment except as provided in 326 IAC 9-1-2 or in this permit.

C.6 Fugitive Dust Emissions [326 IAC 6-4]

The Permittee shall not allow fugitive dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would violate 326 IAC 6-4 (Fugitive Dust Emissions).

C.7 Asbestos Abatement Projects [326 IAC 14-10][326 IAC 18][40 CFR 61, Subpart M]

(a) Notification requirements apply to each owner or operator. If the combined amount of regulated asbestos containing material (RACM) to be stripped, removed or disturbed is at least 260 linear feet on pipes or 160 square feet on other facility components, or at least thirty-five (35) cubic feet on all facility components, then the notification requirements of 326 IAC 14-10-3 are mandatory. All demolition projects require notification whether or not asbestos is present.

(b) The Permittee shall ensure that a written notification is sent on a form provided by the Commissioner at least ten (10) working days before asbestos stripping or removal work or before demolition begins, per 326 IAC 14-10-3, and shall update such notice as necessary, including, but not limited to the following:

(1) When the amount of affected asbestos containing material increases or decreases by at least twenty percent (20%); or

(2) If there is a change in the following:

(A) Asbestos removal or demolition start date;

(B) Removal or demolition contractor; or

(C) Waste disposal site.

(c) The Permittee shall ensure that the notice is postmarked or delivered according to the guidelines set forth in 326 IAC 14-10-3(2).

(d) The notice to be submitted shall include the information enumerated in 326 IAC 14-10-3(3).

All required notifications shall be submitted to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality

100 North Senate Avenue

MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

The notice shall include a signed certification from the owner or operator that the information provided in this notification is correct and that only Indiana licensed workers and project supervisors will be used to implement the asbestos removal project. The notifications do not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(e) Procedures for Asbestos Emission Control
The Permittee shall comply with the applicable emission control procedures in 326 IAC 14-10-4 and 40 CFR 61.145(c). Per 326 IAC 14-10-1, emission control requirements are applicable for any removal or disturbance of RACM greater than three (3) linear feet on pipes or three (3) square feet on any other facility components or a total of at least 0.75 cubic feet on all facility components.

(f) Demolition and Renovation
The Permittee shall thoroughly inspect the affected facility or part of the facility where the demolition or renovation will occur for the presence of asbestos pursuant to 40 CFR 61.145(a).

(g) Indiana Licensed Asbestos Inspector
The Permittee shall comply with 326 IAC 14-10-1(a) that requires the owner or operator, prior to a renovation/demolition, to use an Indiana Licensed Asbestos Inspector to thoroughly inspect the affected portion of the facility for the presence of asbestos.

Testing Requirements [326 IAC 2-8-4(3)]

C.8 Performance Testing [326 IAC 3-6]

(a) For performance testing required by this permit, a test protocol, except as provided elsewhere in this permit, shall be submitted to:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

no later than thirty-five (35) days prior to the intended test date. The protocol submitted by the Permittee does not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(b) The Permittee shall notify IDEM, OAQ of the actual test date at least fourteen (14) days prior to the actual test date. The notification submitted by the Permittee does not require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

(c) Pursuant to 326 IAC 3-6-4(b), all test reports must be received by IDEM, OAQ not later than forty-five (45) days after the completion of the testing. An extension may be granted by IDEM, OAQ if the Permittee submits to IDEM, OAQ a reasonable written explanation not later than five (5) days prior to the end of the initial forty-five (45) day period.

Compliance Requirements [326 IAC 2-1.1-11]

C.9 Compliance Requirements [326 IAC 2-1.1-11]

The commissioner may require stack testing, monitoring, or reporting at any time to assure compliance with all applicable requirements by issuing an order under 326 IAC 2-1.1-11. Any monitoring or testing shall be performed in accordance with 326 IAC 3 or other methods approved by the commissioner or the U. S. EPA.

Compliance Monitoring Requirements [326 IAC 2-8-4][326 IAC 2-8-5(a)(1)]

C.10 Compliance Monitoring [326 IAC 2-8-4(3)][326 IAC 2-8-5(a)(1)]

Unless otherwise specified in this permit, for all monitoring requirements not already legally required, the Permittee shall be allowed up to ninety (90) days from the date of permit issuance or of initial start-up, whichever is later, to begin such monitoring. If due to circumstances beyond the Permittee's control, any monitoring equipment required by this permit cannot be installed and operated no later than ninety (90) days after permit issuance or the date of initial startup, whichever is later, the Permittee may extend the compliance schedule related to the equipment for an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

in writing, prior to the end of the initial ninety (90) day compliance schedule, with full justification of the reasons for the inability to meet this date.

The notification which shall be submitted by the Permittee does require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

Unless otherwise specified in the approval for the new emission unit(s), compliance monitoring for new emission units or emission units added through a permit revision shall be implemented when operation begins.

C.11 Instrument Specifications [326 IAC 2-1.1-11][326 IAC 2-8-4(3)][326 IAC 2-8-5(1)]

(a) When required by any condition of this permit, an analog instrument used to measure a parameter related to the operation of an air pollution control device shall have a scale such that the expected maximum reading for the normal range shall be no less than twenty percent (20%) of full scale.

(b) The Permittee may request that the IDEM, OAQ approve the use of an instrument that does not meet the above specifications provided the Permittee can demonstrate that an alternative instrument specification will adequately ensure compliance with permit conditions requiring the measurement of the parameters.

Corrective Actions and Response Steps [326 IAC 2-8-4][326 IAC 2-8-5(a)(1)]

C.12 Risk Management Plan [326 IAC 2-8-4][40 CFR 68]

If a regulated substance, as defined in 40 CFR 68, is present at a source in more than a threshold quantity, the Permittee must comply with the applicable requirements of 40 CFR 68.

C.13 Response to Excursions or Exceedances [326 IAC 2-8-4][326 IAC 2-8-5]

Upon detecting an excursion where a response step is required by the D Section or an exceedance of a limitation in this permit:

(a) The Permittee shall take reasonable response steps to restore operation of the emissions unit (including any control device and associated capture system) to its normal or usual manner of operation as expeditiously as practicable in accordance with good air pollution control practices for minimizing excess emissions.

(b) The response shall include minimizing the period of any startup, shutdown or malfunction. The response may include, but is not limited to, the following:

(1) initial inspection and evaluation;

(2) recording that operations returned or are returning to normal without operator action (such as through response by a computerized distribution control system); or

(3) any necessary follow-up actions to return operation to normal or usual manner of operation.

(c) A determination of whether the Permittee has used acceptable procedures in response to an excursion or exceedance will be based on information available, which may include, but is not limited to, the following:

(1) monitoring results;

(2) review of operation and maintenance procedures and records; and/or

(3) inspection of the control device, associated capture system, and the process.

(d) Failure to take reasonable response steps shall be considered a deviation from the permit.

(e) The Permittee shall record the reasonable response steps taken.

C.14 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-8-4][326 IAC 2-8-5]

(a) When the results of a stack test performed in conformance with Section C - Performance Testing, of this permit exceed the level specified in any condition of this permit, the Permittee shall submit a description of its response actions to IDEM, OAQ, no later than seventy-five (75) days after the date of the test.

(b) A retest to demonstrate compliance shall be performed no later than one hundred eighty (180) days after the date of the test. Should the Permittee demonstrate to IDEM, OAQ that retesting in one hundred eighty (180) days is not practicable, IDEM, OAQ may extend the retesting deadline

(c) IDEM, OAQ reserves the authority to take any actions allowed under law in response to noncompliant stack tests.

The response action documents submitted pursuant to this condition do require a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1).

Record Keeping and Reporting Requirements [326 IAC 2-8-4(3)]

C.15 General Record Keeping Requirements [326 IAC 2-8-4(3)][326 IAC 2-8-5]

(a) Records of all required monitoring data, reports and support information required by this permit shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. Support information includes the following:

(AA) All calibration and maintenance records.
(BB) All original strip chart recordings for continuous monitoring instrumentation.
(CC) Copies of all reports required by the FESOP.

Records of required monitoring information include the following:

(AA) The date, place, as defined in this permit, and time of sampling or measurements.
(BB) The dates analyses were performed.
(CC) The company or entity that performed the analyses.
(DD) The analytical techniques or methods used.
(EE) The results of such analyses.
(FF) The operating conditions as existing at the time of sampling or measurement.

These records shall be physically present or electronically accessible at the source location for a minimum of three (3) years. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.

(b) Unless otherwise specified in this permit, for all record keeping requirements not already legally required, the Permittee shall be allowed up to ninety (90) days from the date of permit issuance or the date of initial start-up, whichever is later, to begin such record keeping.

C.16 General Reporting Requirements [326 IAC 2-8-4(3)(C)][326 IAC 2-1.1-11]

(a) The Permittee shall submit the attached Quarterly Deviation and Compliance Monitoring Report or its equivalent. Proper notice submittal under Section B -Emergency Provisions satisfies the reporting requirements of this paragraph. Any deviation from permit requirements, the date(s) of each deviation, the cause of the deviation, and the response steps taken must be reported except that a deviation required to be reported pursuant to an applicable requirement that exists independent of this permit, shall be reported according to the schedule stated in the applicable requirement and does not need to be included in this report. This report shall be submitted not later than thirty (30) days after the end of the reporting period. The Quarterly Deviation and Compliance Monitoring Report shall include a certification that meets the requirements of 326 IAC 2-8-5(a)(1) by an "authorized individual" as defined by 326 IAC 2-1.1-1(1). A deviation is an exceedance of a permit limitation or a failure to comply with a requirement of the permit.

(b) The address for report submittal is:

Indiana Department of Environmental Management
Compliance and Enforcement Branch, Office of Air Quality
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251

(c) Unless otherwise specified in this permit, any notice, report, or other submission required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ on or before the date it is due.

(d) Reporting periods are based on calendar years, unless otherwise specified in this permit. For the purpose of this permit "calendar year" means the twelve (12) month period from January 1 to December 31 inclusive.

Stratospheric Ozone Protection

C.17 Compliance with 40 CFR 82 and 326 IAC 22-1

Pursuant to 40 CFR 82 (Protection of Stratospheric Ozone), Subpart F, except as provided for motor vehicle air conditioners in Subpart B, the Permittee shall comply with applicable standards for recycling and emissions reduction.

SECTION D.1 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and with chamber exhaust vents (back vents) exhausting to one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01. Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004;

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02;

(c) Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, of which zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01; and

Under 40 CFR 63, Subpart O, emission units (a), (b), and (c) listed above are considered affected facilities. [40 CFR 63, Subpart O][326 IAC 20-5]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-8-4(1)]

D.1.1 Ethylene Oxide [326 IAC 8-1-6]

Pursuant to FESOP F105-8436-00030, issued on February 16, 1998, and 326 IAC 8-1-6, the following control technology will also serve as the Best Available Control Technology (BACT) for the sterilization operations S1 through S7. The control technology used to comply with the requirements of 40 CFR 63.360 through 63.367, which apply to the sterilization process, in addition to the following:

(a) A single nonregenerable dry bed reactor to reduce ethylene oxide emissions to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, to control the seven (7) sterilization chamber exhaust vents, identified as units S1 through S7.

(b) A wet acid pre-scrubber with three (3) dry bed reactors (in parallel) with a control efficiency of 99% to control emissions from the fourteen (14) aeration rooms.

The requirements listed above will control ethylene oxide emissions from the sterilization operations S1 through S7 such that ethylene oxide emissions from S1 through S7 shall not exceed 0.38 tons per year.

Since the requirement to operate the dry bed reactor controlling the emissions from the sterilization chamber exhaust vents (back vents) in the original FESOP was also part of the requirements to satisfy 326 IAC 8-1-6 (New Facilities, General Reduction Requirements), the

source is still required to operate the dry bed reactor controlling emissions from the sterilization chamber exhaust vents (back vents) for units S1 through S7 in order to comply with 326 IAC 8-1-6, even though a control for emissions from back vents is not required by NESHAP Subpart O [40 CFR 63.36]; the source is also required to operate the primary wet acid scrubber to control emissions from the sterilization chambers, as well as the wet acid pre-scrubber and three (3) dry bed reactors (in parallel) to control emissions from the fourteen (14) aerations rooms in order to comply with 326 IAC 8-1-6 (New Facilities, General Reduction Requirements).

Note: Sterilizers S8 and S9 were approved for construction in 2012 and are not subject to the requirements of 326 IAC 8-1-6. However, the Permittee has voluntarily elected to install three (3) non-regenerable dry bed reactors to control emissions from the sterilization chamber exhaust vents (back vents) from the two (2) sterilizers S8 and S9.

D.1.2 Hazardous Air Pollutants (HAPs) [326 IAC 2-8-4]

Pursuant to 326 IAC 2-8, the total ethylene oxide emissions from the nine (9) ethylene oxide sterilization chambers and the fourteen (14) aeration rooms shall be less than 9.40 tons per twelve (12) consecutive month period, total, with compliance determined at the end of each month

Compliance with the above limit, combined with the potential to emit ethylene oxide from other emission units at the source, shall limit the ethylene oxide from the entire source to less than 10 tons per twelve (12) consecutive month period, total HAPs to less than twenty-five (25) tons per 12 consecutive month period, and render 326 IAC 2-7 (Part 70 Permits) and 326 IAC 2-4.1 (Major Sources of Hazardous Air Pollutants (HAP) not applicable.

D.1.3 Preventive Maintenance Plan [326 IAC 2-8-4(9)]

A Preventive Maintenance Plan is required for this facility and any control devices. Section B - Preventive Maintenance Plan contains the Permittee's obligation with regard to the preventive maintenance plan required by this condition.

Compliance Determination Requirements [326 IAC 2-8-4][326 IAC 2-8-5(a)(1)]

D.1.4 Ethylene Oxide Control [326 IAC 8-1-6][326 IAC 2-8-4]

(a) In order to comply with Conditions D.1.1, and D.1.2, the primary wet acid scrubber and the single non-regenerable dry bed reactor shall be in operation and control emissions from the seven (7) ethylene oxide sterilization chambers S1 through S7 at all times the ethylene oxide sterilization chambers are in operation.

(b) In order to comply with Conditions D.1.1, and D.1.2, the primary wet acid scrubber shall be in operation and control emissions from the two (2) ethylene oxide sterilization chambers S8 and S9 at all times the ethylene oxide sterilization chambers are in operation.

(c) In order to comply with Conditions D.1.1, and D.1.2, the three (3) dry bed reactors with or without the wet acid pre-scrubber shall be in operation and control emissions from the fourteen (14) aeration rooms at all times the fourteen (14) aeration rooms are in operation.

D.1.5 Testing Requirements [326 IAC 2-8-5(a)(1)][326 IAC 2-1.1-11][40 CFR Part 63, Subpart O]

In order to demonstrate the compliance status with Condition D.1.1, Condition D.1.2, and Condition E.1.2, not later than 180 days after the startup of sterilization chambers S8 and S9, the Permittee shall perform a performance test on each of the following control devices:

(a) The one (1) primary wet acid scrubber, exhausting to stack PS01, controlling ethylene oxide emissions from the nine (9) sterilization chamber S1 through S9;

(b) The one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), exhausting to stack HV01, controlling ethylene oxide emissions from the fourteen (14) aeration rooms;

using the procedures listed in 40 CFR 63.7 of Subpart A, the procedures listed in 40 CFR 63.363, and the test methods listed in 40 CFR 63.365. During the performance test, the owner or operator shall determine the efficiency of the control devices and the site-specific operating parameters for each of the wet acid scrubbers and the dry bed reactors. This test shall be repeated at least once every five (5) years the date of the most recent valid compliance demonstration. Testing shall be conducted in accordance with the provisions of 326 IAC 3-6 (Source Sampling Procedures). Section C - Performance Testing contains the Permittee's obligation with regard to the performance testing required by this condition.

Compliance Monitoring Requirements [326 IAC 2-8-4][326 IAC 2-8-5(a)(1)]

D.1.6 Monitoring

To demonstrate the compliance status with the control efficiency and emission limitations requirements in conditions D.1.1, and D.1.2:

(a) for the single non-regenerable dry bed reactor controlling ethylene oxide emissions from the seven (7) sterilization chamber exhaust vents (back vents) for units S1 through S7, the Permittee shall monitor and record the number of equivalent sterilization cycles performed while the bed is in service.

(b) The Permittee shall keep a record of the number of sterilization cycles run for sterilizer units S1 through S7, convert this to equivalent cycles for a 512 ft^3 sterilizer, and keep a daily running record of total equivalent cycles. Upon reaching 2,917 equivalent sterilization cycles, based on the manufacturer's guaranteed bed capacity of 360 pounds of ethylene oxide, the performance of the dry bed reactor is assumed to drop below 99% removal efficiency and the bed material will have to be removed and replaced with fresh reactant.

Record Keeping and Reporting Requirements [326 IAC 2-8-4(3)][326 IAC 2-8-16]

D.1.7 Record Keeping Requirements

(a) To document the compliance status with Conditions D.1.1, D.1.2, and D.1.6, the Permittee shall maintain records in accordance with (1) and (2) below. Records maintained for (1) shall be taken daily and shall be complete and sufficient to establish compliance with the ethylene oxide emission limits and/or control efficiency limits established in Conditions D.1.1, and D.1.2, and the monitoring requirements established in Condition D.1.6. Records maintained for (2) shall be taken daily and shall be used for reference purposes only. Records necessary to demonstrate compliance shall be available within 30 days of the end of each compliance period.

(1) The number of equivalent sterilization cycles performed daily while the single non-regenerable dry bed reactor controlling chamber exhaust vents is in service; and

(2) The number of equivalent sterilization cycles performed daily while the three (3) dry bed reactors controlling aeration room exhaust are in service.

(b) Section C - General Record Keeping Requirements, of this permit contains the Permittee's obligations with regard to the records required by this condition.

SECTION D.2 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

(h) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment; [326 IAC 6-3-2]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-8-4(1)]

D.2.1 Particulate [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2(e)(2), the particulate emissions from the brazing equipment, cutting torches, soldering equipment and welding equipment shall not exceed 0.551 pound per hour.

SECTION D.3 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

(e) Natural gas fired combustion sources with a total heat input of 20.45 MMBtu per hour, including the following:

(1) One natural gas-fired boiler, identified as C238-F, constructed in 2000, with a maximum heat input capacity of 0.45 MMBtu per hour;

(2) One natural gas-fired boiler, identified as C240-F, constructed in 2003, with a maximum heat input capacity of 1.26 MMBtu per hour;

(3) One natural gas-fired boiler, identified as C241-F, constructed in 2003, with a maximum heat input capacity of 2.1349 MMBtu per hour;

(4) One natural gas-fired boiler, identified as C242-F, constructed in 2003, with a maximum heat input capacity of 2.1349 MMBtu per hour;

(5) One natural gas-fired boiler, identified as C239-F, constructed in 2004, with a maximum heat input capacity of 1.26 MMBtu per hour;

(6) One natural gas-fired boiler, identified as C246-F, constructed in 2004, with a maximum heat input capacity of 1.5 MMBtu per hour;

(7) One natural gas-fired boiler, identified as C230-F, constructed in 2006, with a maximum heat input capacity of 1.68 MMBtu per hour;

(8) One natural gas-fired boiler, identified as C231-F, constructed in 2006, with a maximum heat input capacity of 1.68 MMBtu per hour;

(9) One natural gas-fired boiler, identified as C232-F, constructed in 2006, with a maximum heat input capacity of 7.0 MMBtu per hour;

(10) One natural gas-fired boiler, identified as C233-F, constructed in 2006, with a maximum heat input capacity of 0.85 MMBtu per hour;

(11) One natural gas-fired boiler, identified as C364-F, constructed in 2010, with a maximum heat input capacity of 0.5 MMBtu per hour;

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-8-4(1)]

D.3.1 Particulate Matter [326 IAC 6-2]

Pursuant to 326 IAC 6-2-4, particulate emissions from each individual boiler shall be limited as follows:

Unit ID	PM Emission Limit (lb/MMBtu)
C238-F	0.6
C240-F	0.6
C241-F	0.6
C242-F	0.6
C239-F	0.6
C246-F	0.6
C230-F	0.5
C231-F	0.5
C232-F	0.5
C233-F	0.5
C364-F	0.5

Particulate emissions from indirect heating facilities constructed after September 21, 1983 shall be limited by the following equation:

$$Pt = \frac{1.09}{Q^{0.26}}$$

Pt = pounds of particulate matter emitted per million Btu (lb/MMBtu) heat input.
Q = Total source maximum operating capacity in MMBtu/hr heat input. Maximum operating capacity is defined as the maximum capacity at which the unit is operated or the nameplate capacity, whichever is specified in the permit application, except when a lower limitation is contained in the facility's operating permit.

SECTION E.1 SOURCE OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

(a) Seven (7) ethylene oxide sterilization chambers, identified as S1 through S7, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, all exhausting to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01, and with chamber exhaust vents (back vents) exhausting to one (1) single non-regenerable dry bed reactor which exhausts through one (1) stack, identified as SV01. Sterilization chambers S1 through S6 were constructed in 1998 and sterilization chamber S7 was constructed in 2004;

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02;

(c) Fourteen (14) aeration rooms, identified as HC1 through HC14, all constructed in 1998, of which zero (0) to a maximum of six (6) can exhaust through one (1) wet acid pre-scrubber and three (3) dry bed reactors (in parallel), with the remaining units exhausting solely through the three (3) dry bed reactors (in parallel), all of which exhaust through one (1) stack, identified as HV01; and

Under 40 CFR 63, Subpart O, emission units (a), (b), and (c) listed above are considered affected facilities. [40 CFR 63, Subpart O][326 IAC 20-5]

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

National Emission Standards for Hazardous Air Pollutants (NESHAP) Requirements

E.1.1 General Provisions Relating to NESHAP O [326 IAC 20-1][40 CFR Part 63, Subpart A]

The requirements of 40 CFR Part 63, Subpart A - General Provisions, which are incorporated as 326 IAC 20-1-1, apply to the facilities described in this section except as otherwise specified in 40 CFR 63, Subpart O.

E.1.2 Ethylene Oxide Emissions Standards for Sterilization Facilities NESHAP [40 CFR Part 63, Subpart O][326 IAC 20-5]

The Permittee which owns or operates stationary ethylene oxide sterilization facility at an area source of HAP emissions shall comply with the following provisions of 40 CFR Part 63, Subpart O as follows:

(1) 40 CFR 63.360,
(2) 40 CFR 63.361,
(3) 40 CFR 63.362,
(4) 40 CFR 63.363(a), (b)(1), (b)(2), (c), (e), (f),
(5) 40 CFR 63.364(a), (b), (d), (e),
(6) 40 CFR 63.365,
(7) 40 CFR 63.366,
(8) 40 CFR 63.367,
(9) 40 CFR 63.368.

SECTION E.2 EMISSIONS UNIT OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

(e) One (1) diesel-fired emergency generator, identified as Unit #1, installed on July 31, 2003 and approved for construction in 2010, with a maximum capacity of 1850 hp, with emissions uncontrolled, and exhausting to the atmosphere.

This unit is considered an existing affected facility under 40 CFR 63, Subpart ZZZZ.

(f) One (1) diesel-fired emergency generator, identified as Unit #2, installed on November 19, 2003 and approved for construction in 2010, with a maximum capacity of 2922 hp, with emissions uncontrolled, and exhausting to the atmosphere.

This unit is considered an existing affected facility under 40 CFR 63, Subpart ZZZZ.

(The information describing the process contained in this emissions unit description box is descriptive information and does not constitute enforceable conditions.)

National Emission Standards for Hazardous Air Pollutants (NESHAP) Requirements

E.2.1 General Provisions Relating to NESHAP ZZZZ [326 IAC 20-1][40 CFR Part 63, Subpart A]

The provisions of 40 CFR Part 63, Subpart A - General Provisions, which are incorporated by reference as 326 IAC 20-1-1, apply to the facilities described in this section except when otherwise specified in 40 CFR Part 63, Subpart ZZZZ.

E.2.2 National Emission Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines [326 IAC 20-82][40 CFR 63, Subpart ZZZZ]

The Permittee which owns or operates a stationary RICE at an area source of HAP emissions shall comply with the following provisions of 40 CFR Part 63, Subpart ZZZZ:

(1) 40 CFR 63.6580
(2) 40 CFR 63.6585
(3) 40 CFR 63.6590(a)(1)(iii), (b)(3)

The entire text of 40 CFR 63, Subpart ZZZZ is included as Attachment B to this permit.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY

FEDERALLY ENFORCEABLE STATE OPERATING PERMIT (FESOP) CERTIFICATION

Source Name: Cook Incorporated
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP Permit No.: F105-27381-00030

This certification shall be included when submitting monitoring, testing reports/results or other documents as required by this permit.

Please check what document is being certified:

- ☐ Annual Compliance Certification Letter
- ☐ Test Result (specify)_____
- ☐ Report (specify)_____
- ☐ Notification (specify)_____
- ☐ Affidavit (specify)_____
- ☐ Other (specify)_____

I certify that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

Signature:

Printed Name:

Title/Position:

Date:

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE AND ENFORCEMENT BRANCH
100 North Senate Avenue
MC 61-53 IGCN 1003
Indianapolis, Indiana 46204-2251
Phone: (317) 233-0178
Fax: (317) 233-6865

FEDERALLY ENFORCEABLE STATE OPERATING PERMIT (FESOP)
EMERGENCY OCCURRENCE REPORT

Source Name: Cook Incorporated
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP Permit No.: F105-27381-00030

This form consists of 2 pages **Page 1 of 2**

☐ This is an emergency as defined in 326 IAC 2-7-1(12)
- The Permittee must notify the Office of Air Quality (OAQ), within four (4) daytime business hours (1-800-451-6027 or 317-233-0178, ask for Compliance Section); and
- The Permittee must submit notice in writing or by facsimile within two (2) working days (Facsimile Number: 317-233-6865), and follow the other requirements of 326 IAC 2-7-16

If any of the following are not applicable, mark N/A

Facility/Equipment/Operation:
Control Equipment:
Permit Condition or Operation Limitation in Permit:
Description of the Emergency:
Describe the cause of the Emergency:

If any of the following are not applicable, mark N/A **Page 2 of 2**

Date/Time Emergency started:
Date/Time Emergency was corrected:
Was the facility being properly operated at the time of the emergency? Y N Describe:
Type of Pollutants Emitted: TSP, PM-10, SO_2, VOC, NO_x, CO, Pb, other:
Estimated amount of pollutant(s) emitted during emergency:
Describe the steps taken to mitigate the problem:
Describe the corrective actions/response steps taken:
Describe the measures taken to minimize emissions:
If applicable, describe the reasons why continued operation of the facilities are necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw materials of substantial economic value:

Form Completed by:_____

Title / Position:_____

Date:_____

Phone: _____

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE AND ENFORCEMENT BRANCH
FEDERALLY ENFORCEABLE STATE OPERATING PERMIT (FESOP)
QUARTERLY DEVIATION AND COMPLIANCE MONITORING REPORT

Source Name: Cook Incorporated
Source Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
FESOP Permit No.: F105-27381-00030

Months: _____ **to** _____ **Year:** _____

This report shall be submitted quarterly based on a calendar year. Proper notice submittal under Section B -Emergency Provisions satisfies the reporting requirements of paragraph (a) of Section C-General Reporting. Any deviation from the requirements of this permit, the date(s) of each deviation, the probable cause of the deviation, and the response steps taken must be reported. A deviation required to be reported pursuant to an applicable requirement that exists independent of the permit, shall be reported according to the schedule stated in the applicable requirement and does not need to be included in this report. Additional pages may be attached if necessary. If no deviations occurred, please specify in the box marked "No deviations occurred this reporting period".
☐ NO DEVIATIONS OCCURRED THIS REPORTING PERIOD.
☐ THE FOLLOWING DEVIATIONS OCCURRED THIS REPORTING PERIOD
Permit Requirement (specify permit condition #)
Date of Deviation: / **Duration of Deviation:**
Number of Deviations:
Probable Cause of Deviation:
Response Steps Taken:
Permit Requirement (specify permit condition #)
Date of Deviation: / **Duration of Deviation:**
Number of Deviations:
Probable Cause of Deviation:
Response Steps Taken:

Page 2 of 2

Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	
Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	
Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	

Form Completed by:_____

Title / Position:_____

Date:_____

Phone: _____

Indiana Department of Environmental Management
Office of Air Quality

Technical Support Document (TSD) for an Administrative Amendment to a Federally Enforceable State Operating Permit (FESOP) Renewal

Source Description and Location

Source Name:	**Cook Incorporated**
Source Location:	**6330 North Matthews Drive, Ellettsville, Indiana 47429**
County:	**Monroe**
SIC Code:	**3841 (Surgical and Medical Instruments and Apparatus)**
Operation Permit No.:	**F105-27381-00030**
Operation Permit Issuance Date:	**August 24, 2009**
Administrative Amendment No.:	**105-41050-00030**
Permit Reviewer:	**Tamara Havics**

Existing Approvals

The source was issued FESOP Renewal No. F105-27381-00030 on August 24, 2009. The source has since received the following approvals:

(a) Significant Permit Revision No. 105-29042-00030, issued June 25, 2010.
(b) Interim Significant Permit Revision No. 105-32055i-00030, issued July 25, 2012.
(c) Significant Permit Revision No. 105-32055-00030, issued September 7, 2012.

The source submitted an application for a FESOP Renewal on November 11, 2018. At this time, this application is under review.

County Attainment Status

The source is located in Monroe County.

Pollutant	Designation
SO_2	Better than national standards.
CO	Unclassifiable or attainment effective November 15, 1990.
O_3	Unclassifiable or attainment effective July 20, 2012, for the 2008 8-hour ozone standard.[1]
$PM_{2.5}$	Unclassifiable or attainment effective April 5, 2005, for the annual $PM_{2.5}$ standard.
$PM_{2.5}$	Unclassifiable or attainment effective December 13, 2009, for the 24-hour $PM_{2.5}$ standard.
PM_{10}	Unclassifiable effective November 15, 1990.
NO_2	Cannot be classified or better than national standards.
Pb	Unclassifiable or attainment effective December 31, 2011.

[1]Unclassifiable or attainment effective October 18, 2000, for the 1-hour ozone standard which was revoked effective June 15, 2005.

(a) Ozone Standards
Volatile organic compounds (VOC) and Nitrogen Oxides (NO_x) are regulated under the Clean Air Act (CAA) for the purposes of attaining and maintaining the National Ambient Air Quality Standards (NAAQS) for ozone. Therefore, VOC and NO_x emissions are considered when evaluating the rule applicability relating to ozone. Monroe County has been designated as attainment or unclassifiable for ozone. Therefore, VOC and NO_x emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

(b) $PM_{2.5}$
Monroe County has been classified as attainment for $PM_{2.5}$. Therefore, direct $PM_{2.5}$, SO_2, and NOx emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

(c) Other Criteria Pollutants
Monroe County has been classified as attainment or unclassifiable in Indiana for all the other criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

Fugitive Emissions

Since this type of operation is not one (1) of the twenty-eight (28) listed source categories under 326 IAC 2-2-1(ff)(1), 326 IAC 2-3-2(g), or 326 IAC 2-7-1(22)(B), and there is no applicable New Source Performance Standard or National Emission Standard for Hazardous Air Pollutants that was in effect on August 7, 1980, fugitive emissions are not counted toward the determination of PSD, Emission Offset, and Part 70 Permit applicability.

The fugitive emissions of hazardous air pollutants (HAP) are counted toward the determination of Part 70 Permit applicability and source status under Section 112 of the Clean Air Act (CAA).

Greenhouse Gas (GHG) Emissions

On June 23, 2014, in the case of *Utility Air Regulatory Group v. EPA*, cause no. 12-1146, (available at http://www.supremecourt.gov/opinions/13pdf/12-1146_4g18.pdf) the United States Supreme Court ruled that the U.S. EPA does not have the authority to treat greenhouse gases (GHGs) as an air pollutant for the purpose of determining operating permit applicability or PSD Major source status. On July 24, 2014, the U.S. EPA issued a memorandum to the Regional Administrators outlining next steps in permitting decisions in light of the Supreme Court's decision. U.S. EPA's guidance states that U.S. EPA will no longer require PSD or Title V permits for sources "previously classified as 'Major' based solely on greenhouse gas emissions."

The Indiana Environmental Rules Board adopted the GHG regulations required by U.S. EPA at 326 IAC 2-2-1(zz), pursuant to Ind. Code § 13-14-9-8(h) (Section 8 rulemaking). A rule, or part of a rule, adopted under Section 8 is automatically invalidated when the corresponding federal rule, or part of the rule, is invalidated. Due to the United States Supreme Court Ruling, IDEM, OAQ cannot consider GHG emissions to determine operating permit applicability or PSD applicability to a source or modification.

Source Status - Existing Source

The table below summarizes the potential to emit of the entire source, prior to the administrative amendment, after consideration of all enforceable limits established in the effective permits. If the control equipment has been determined to be integral, the table reflects the potential to emit (PTE) after consideration of the integral control device.

	Source-Wide Emissions Prior to Administrative Amendment (ton/year)								
	PM[1]	PM_{10}[1]	$PM_{2.5}$[1, 2]	SO_2	NOx	VOC	CO	Single HAP[3]	Total HAPs
Total PTE of Entire Source Excluding Fugitive Emissions*	**1.14**	**1.29**	**1.29**	**4.88**	**37.41**	**28.22**	**13.94**	**9.40**	**9.88**
Title V Major Source Thresholds	NA	100	100	100	100	100	100	10	25
PSD Major Source Thresholds	250	250	250	250	250	250	250	--	--

[1]Under the Part 70 Permit program (40 CFR 70), PM_{10} and $PM_{2.5}$, not particulate matter (PM), are each considered as a "regulated air pollutant."

[2]$PM_{2.5}$ listed is direct $PM_{2.5}$.

[3]Single highest source-wide HAP =Ethylene Oxide

*Fugitive HAP emissions are always included in the source-wide emissions.

(a) This existing source is not a major stationary source, under PSD (326 IAC 2-2), because no PSD regulated pollutant is emitted at a rate of two hundred fifty (250) tons per year or more and it is not one of the twenty-eight (28) listed source categories, as specified in 326 IAC 2-2-1(ff)(1).

(b) This existing source is not a major source of HAP, as defined in 40 CFR 63.2, because HAP emissions are less than ten (10) tons per year for any single HAP and less than twenty-five (25) tons per year of a combination of HAPs.

(c) These emissions are based on the TSD of FESOP SPR No. 105-32055-00030, issued on September 7, 2012.

Description of Amendment

The Office of Air Quality (OAQ) has reviewed an application submitted by Cook Incorporated on January 2, 2019, relating to the addition of voluntary emissions control equipment. Cook Incorporated has proposed the installation of three new DR-490 dry beds with sufficient capacity to handle chamber exhaust vent emissions of ethylene oxide from Sterilizers S8 and S9, with a minimum removal efficiency of 99%.

The following is a list of the modified emission units and pollution control device(s):

(a) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02.

Enforcement Issues

There are no pending enforcement actions related to this administrative amendment.

Emission Calculations

See Appendix A of this Technical Support Document for detailed emission calculations.

Permit Level Determination – FESOP Administrative Amendment

Pursuant to 326 IAC 2-1.1-1(12), Potential to Emit is defined as "the maximum capacity of a stationary source or emission unit to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U. S. EPA, IDEM, or the appropriate local air pollution control agency."

The following table is used to determine the appropriate permit level under 326 IAC 2-8-10 (Administrative Permit Amendments). This table reflects the PTE before controls of the administrative amendment. If the control equipment has been determined to be integral, the table reflects the potential to emit (PTE) after consideration of the integral control device.

	PTE Increase of the Modified Emission Unit(s)/Process(es) (ton/year)								
Process / Emission Unit	**PM**	**PM_{10}**	**$PM_{2.5}$[1]**	**SO_2**	**NO_X**	**VOC**	**CO**	**Single HAP[2]**	**Total HAPs**
PTE Before Modification Sterilization (S8 to S9)	-	-	-	-	-	9.40	-	9.40	9.40
PTE After Modification Sterilization (S8 to S9)	-	-	-	-	-	9.40	-	9.40	9.40
Total PTE Increase of the Modified Emission Unit(s)/Process	-	-	-	-	-	**0**	-	**0**	**0**

[1]$PM_{2.5}$ listed is direct $PM_{2.5}$.

[2]Single highest HAP = ethylene oxide

Appendix A of this TSD reflects the detailed potential emissions of the administrative amendment.

Pursuant to 326 IAC 2-8-10(a)(2)(B), this change to the permit is considered an administrative amendment because the permit is amended to change descriptive information concerning the source or an emissions unit, where the revision will not trigger a new applicable requirement. The Permittee is adding voluntary emission control equipment.

(a) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to **three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02**~~Stacks CEV01 and CEV02, respectively, using no control~~;

See Appendix A for the revised controlled potential to emit of the source.

PTE of the Entire Source After Issuance of the FESOP Administrative Amendment

The table below summarizes the after issuance source-wide potential to emit, reflecting all limits, of the emission units. Any control equipment is considered federally enforceable only after issuance of the administrative amendment, and only to the extent that the effect of the control equipment is made

practically enforceable in the permit. If the control equipment has been determined to be integral, the table reflects the potential to emit (PTE) after consideration of the integral control device.

	Source-Wide Emissions After Issuance (ton/year)								
	PM[1]	PM_{10}[1]	$PM_{2.5}$[1, 2]	SO_2	NOx	VOC	CO	Single HAP[3]	Total HAPs
Total PTE of Entire Source Excluding Fugitive Emissions*	**1.14**	**1.29**	**1.29**	**4.88**	**37.41**	**28.22**	**13.94**	**9.40**	**9.88**
Title V Major Source Thresholds	NA	100	100	100	100	100	100	10	25
PSD Major Source Thresholds	250	250	250	250	250	250	250	--	--

[1]Under the Part 70 Permit program (40 CFR 70), PM_{10} and $PM_{2.5}$, not particulate matter (PM), are each considered as a "regulated air pollutant."

[2]$PM_{2.5}$ listed is direct $PM_{2.5}$.

[3]Single highest source-wide HAP =Ethylene Oxide

*Fugitive HAP emissions are always included in the source-wide emissions.

Appendix A of this TSD reflects the detailed potential to emit of the entire source after issuance.

(a) This existing Title V minor stationary source will continue to be minor under 326 IAC 2-7 because the potential to emit criteria pollutants and HAPs from the entire source will continue to be less than or limited to less than the Title V major source threshold levels. Therefore, the source is subject to the provisions of 326 IAC 2-8 (FESOP) and is an area source under Section 112 of the Clean Air Act (CAA).

(b) This existing minor PSD stationary source will continue to be minor under 326 IAC 2-2 because the potential to emit of all PSD regulated pollutants from the entire source will continue to be less than the PSD major source thresholds. Therefore, pursuant to 326 IAC 2-2, the PSD requirements do not apply.

Federal Rule Applicability Determination

Due to the administrative amendment, federal rule applicability has been reviewed as follows:

New Source Performance Standards (NSPS):

There are no New Source Performance Standards (NSPS) (326 IAC 12 and 40 CFR Part 60) included in the permit for this administrative amendment.

National Emission Standards for Hazardous Air Pollutants (NESHAP):

There are no changes to requirements for National Emission Standards for Hazardous Air Pollutants (NESHAPs) (40 CFR Part 63, 326 IAC 14, and 326 IAC 20) included in the permit for this administrative amendment. The two (2) ethylene oxide sterilization chambers, identified as S8 and S9, will continue to be subject to 40 CFR 63, Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities.

Compliance Assurance Monitoring (CAM):

Pursuant to 40 CFR 64.2, Compliance Assurance Monitoring (CAM) is not included in the permit, because the unlimited potential to emit of the source is limited to less than the Title V major source thresholds and the source is not required to obtain a Part 70 or Part 71 permit.

State Rule Applicability

Due to this administrative amendment, state rule applicability has been reviewed as follows:

326 IAC 2-4.1 (Major Sources of Hazardous Air Pollutants (HAP))
The modified emission unit(s) will emit less than ten (10) tons per year for a single HAP and less than twenty-five (25) tons per year for a combination of HAPs. Therefore, 326 IAC 2-4.1 does not apply.

326 IAC 2-8-4 (FESOP)
FESOP applicability is discussed under the PTE of the Entire Source After Issuance of the FESOP Administrative Amendment section of this document.

326 IAC 8-1-6 (VOC Rules: General Reduction Requirements for New Facilities)
Even though Sterilization chambers S8 and S9 are to be constructed after January 1, 1980, they are not subject to the requirements of 326 IAC 8-1-6, because each chamber's unlimited VOC potential emissions is less than twenty-five (25) tons per year.

Compliance Determination and Monitoring Requirements

There are no new or modified compliance requirements included with this administrative amendment.

Proposed Changes

The following changes listed below are due to the administrative amendment. Deleted language appears as ~~strikethrough~~ text and new language appears as **bold** text:

(1) The descriptions in Condition A.2, Section D.1, and Section E.1 have been revised to add the new emissions control equipment.

(2) The note in Condition D.1.1 has been revised.

....

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-8-3(c)(3)]

This stationary source consists of the following emission units and pollution control devices:

....

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to **three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02**~~Stacks CEV01 and CEV02, respectively, using no control~~;

....

SECTION D.1 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

....

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to **three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02**~~Stacks CEV01 and CEV02, respectively, using no control~~;

....

Emission Limitations and Standards [326 IAC 2-8-4(1)]

D.1.1 Ethylene Oxide [326 IAC 8-1-6]

....

Note: ~~The source will not be required to operate the dry bed reactor to control emissions from the sterilization chamber exhaust vents (back vents) from the two (2) sterilizers S8 and S9~~**Sterilizers S8 and S9 were**~~,~~ approved for construction in 2012 **and** ~~, S8 and S9~~ are not subject to the requirements of 326 IAC 8-1-6. **However, the Permittee has voluntarily elected to install three (3) non-regenerable dry bed reactors to control emissions from the sterilization chamber exhaust vents (back vents) from the two (2) sterilizers S8 and S9.**

....

SECTION E.1 SOURCE OPERATION CONDITIONS

Facility Description [326 IAC 2-8-4(10)]:

....

(b) Two (2) ethylene oxide sterilization chambers, identified as S8 and S9, approved for construction in 2012, each using Oxyfume 2000, Oxyfume 2002 or pure ethylene oxide for sterilization, each exhausting through a vacuum pump to one (1) primary wet acid scrubber which exhausts through one (1) stack, identified as PS01; and with S8 and S9 chamber exhaust vents (back vents) exhausting to **three (3) non-regenerable dry bed reactors, which exhaust through one (1) stack, identified as SV02**~~Stacks CEV01 and CEV02, respectively, using no control~~;

....

....

Conclusion and Recommendation

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant. An application for the purposes of this review was received on January 2, 2019.

IDEM Contact

(a) If you have any questions regarding this permit, please contact Tamara Havics, Indiana Department Environmental Management, Office of Air Quality, Permits Branch, 100 North Senate Avenue, MC 61-53 IGCN 1003, Indianapolis, Indiana 46204-2251, or by telephone at (317) 232-8219 or (800) 451-6027, and ask for Tamara Havics or (317) 232-8219.

(b) A copy of the findings is available on the Internet at: http://www.in.gov/ai/appfiles/idem-caats/

(c) For additional information about air permits and how the public and interested parties can participate, refer to the IDEM Air Permits page on the Internet at: http://www.in.gov/idem/airquality/2356.htm; and the Citizens' Guide to IDEM on the Internet at: http://www.in.gov/idem/6900.htm.

Appendix A: Emissions Calculations
Source-Wide Summary

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Administrative Amendment No.: 105-41050-00030
Reviewer: Tamara Havics

Uncontrolled Potential To Emit of the Entire Source (tons/year)									
Process / Emission Unit	**PM**	**PM10**	**PM2.5**	**SO_2**	**NOx**	**VOC**	**CO**	**Total HAPs**	**Highest Single HAP**
Sterilization (S1 to S7)	-	-	-	-	-	37.80	-	37.80	37.80 Ethylene Oxide
Sterilization (S8 to S9)	-	-	-	-	-	24.04	-	24.04	24.04 Ethylene Oxide
Surface Coating	-	-	-	-	-	2.05	-	0.01	0.01 Methanol
Miscellaneous Cleaning with IPA	-	-	-	-	-	9.47	-	-	-
Catheter Impregnation	-	-	-	-	-	0.90	-	0.12	0.12 Methanol
Paclitaxel Treatment	-	-	-	-	-	4.77	-	-	-
Boilers	0.17	0.67	0.67	0.05	8.78	0.48	7.38	0.17	0.16 Hexane
Emergency Diesel Generators	0.84	0.48	0.48	4.83	28.63	0.84	6.56	0.01	6.48E-03 Benzene
Insignificant Activities*	0.14	0.14	0.14	-	-	0.32	-	0.17	0.09 TCE
Total PTE of Entire Source	**1.14**	**1.29**	**1.29**	**4.88**	**37.41**	**80.66**	**13.94**	**62.32**	**61.84 Ethylene Oxide**

This Significant Permit Revision includes the addtion of two (2) new sterilization chambers, with PTE of 24.04 tons per year of VOC and Ethylene Oxide (ETO)
*Insignificant Activity Emissions represent emissions from various assembly operations including gluing, package prep and printing.

Limited Potential To Emit of the Entire Source (tons/year)									
Process / Emission Unit	**PM**	**PM10**	**PM2.5**	**SO_2**	**NOx**	**VOC**	**CO**	**Total HAPs**	**Highest Single HAP**
Sterilization (S1 to S7)	-	-	-	-	-	9.40	-	9.40	9.40 Ethylene Oxide
Sterilization (S8 to S9)	-	-	-	-	-		-		
Surface Coating	-	-	-	-	-	2.05	-	0.01	0.01 Methanol
Miscellaneous Cleaning with IPA	-	-	-	-	-	9.47	-	-	-
Catheter Impregnation	-	-	-	-	-	0.90	-	0.12	0.12 Methanol
Paclitaxel Treatment	-	-	-	-	-	4.77	-	-	-
Boilers	0.17	0.67	0.67	0.05	8.78	0.48	7.38	0.17	0.16 Hexane
Emergency Diesel Generators	0.84	0.48	0.48	4.83	28.63	0.84	6.56	0.01	6.48E-03 Benzene
Insignificant Activities	0.14	0.14	0.14	-	-	0.32	-	0.17	0.09 TCE
Total PTE of Entire Source	**1.14**	**1.29**	**1.29**	**4.88**	**37.41**	**28.22**	**13.94**	**9.88**	**9.40 Ethylene Oxide**

Controlled Potential To Emit of the Entire Source (tons/year)									
Process / Emission Unit	**PM**	**PM10**	**PM2.5**	**SO_2**	**NOx**	**VOC**	**CO**	**Total HAPs**	**Highest Single HAP**
Sterilization (S1 to S7)	-	-	-	-	-	0.38	-	0.38	0.38 Ethylene Oxide
Sterilization (S8 to S9)	-	-	-	-	-	0.29	-	0.29	0.29 Ethylene Oxide
Surface Coating	-	-	-	-	-	2.05	-	0.01	0.01 Methanol
Miscellaneous Cleaning with IPA	-	-	-	-	-	9.47	-	-	-
Catheter Impregnation	-	-	-	-	-	0.90	-	0.12	0.12 Methanol
Paclitaxel Treatment	-	-	-	-	-	4.77	-	-	-
Boilers	0.17	0.67	0.67	0.05	8.78	0.48	7.38	0.17	0.16 Hexane
Emergency Diesel Generators	0.84	0.48	0.48	4.83	28.63	0.84	6.56	0.01	6.48E-03 Benzene
Insignificant Activities	0.14	0.14	0.14	-	-	0.32	-	0.17	0.09 TCE
Total PTE of Entire Source	**1.14**	**1.29**	**1.29**	**4.88**	**37.41**	**19.49**	**13.94**	**1.15**	**0.67 Ethylene Oxide**

Appendix A: Emissions Calculations
HAP Emissions Summary

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Administrative Amendment No.: 105-41050-00030
Reviewer: Tamara Havics

HAP Emissions -Uncontrolled

Equipment Description	PTE (ton/yr)																	
	Ethylene Oxide (EO)	Methanol	Benzene	Dichloro-benzene	Formalde-hyde	Hexane	Toluene	Xylene	Acetalde-hyde	Acrolein	Lead	Cadmium	Chromium	Manganese	Nickel	TCE	Total HAPs	Highest Single HAP
Sterilization S1 through S7	37.80	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	37.80	37.80
Sterilization S8 and S9	24.04	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	24.04	24.04
Plastic Tubing & Metal Wiring	-	7.14E-03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0.01	0.01
Catheter Impregnation	-	1.23E-01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0.12	0.12
Boilers	-	-	1.84E-04	1.05E-04	6.59E-03	1.58E-01	2.99E-04	-	-	-	4.391E-05	9.66E-05	0.0001229	3.3369E-05	1.84E-04	-	0.17	0.16
Diesel Em. Generators	-	-	6.48E-03	-	6.59E-04	-	2.35E-03	1.61E-03	2.10E-04	6.58E-05	-	-	-	-	-	-	0.01	0.01
Package Prep	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	9.00E-02	0.17	0.09
	6.18E+01	1.31E-01	6.66E-03	1.05E-04	7.24E-03	1.58E-01	2.65E-03	1.61E-03	2.10E-04	6.58E-05	4.39E-05	9.66E-05	1.23E-04	3.34E-05	1.84E-04	9.00E-02	62.32	61.84
																		Ethylene Oxide

HAP Emissions - Limited

Equipment Description	PTE (ton/yr)																	
	Ethylene Oxide (EO)	Methanol	Benzene	Dichloro-benzene	Formalde-hyde	Hexane	Toluene	Xylene	Acetalde-hyde	Acrolein	Lead	Cadmium	Chromium	Manganese	Nickel	TCE	Total HAPs	Highest Single HAP
Sterilization S1 through S7	9.40	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	9.40	9.40
Sterilization S8 and S9		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
Plastic Tubing & Metal Wiring	-	7.14E-03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0.01	0.01
Catheter Impregnation	-	1.23E-01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0.12	0.12
Boilers	-	-	1.84E-04	1.05E-04	6.59E-03	1.58E-01	2.99E-04	-	-	-	4.39E-05	9.66E-05	1.23E-04	3.34E-05	1.84E-04	-	0.17	0.16
Diesel Em. Generators	-	-	6.48E-03	-	6.59E-04	-	2.35E-03	1.61E-03	2.10E-04	6.58E-05	-	-	-	-	-	-	0.01	0.01
Package Prep	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	9.00E-02	0.17	0.09
	9.40E+00	1.31E-01	6.66E-03	1.05E-04	7.24E-03	1.58E-01	2.65E-03	1.61E-03	2.10E-04	6.58E-05	4.39E-05	9.66E-05	1.23E-04	3.34E-05	1.84E-04	9.00E-02	9.88	9.40
																		Ethylene Oxide

HAP Emissions -Controlled

Equipment Description	PTE (ton/yr)																	
	Ethylene Oxide (EO)	Methanol	Benzene	Dichloro-benzene	Formalde-hyde	Hexane	Toluene	Xylene	Acetalde-hyde	Acrolein	Lead	Cadmium	Chromium	Manganese	Nickel	TCE	Total HAPs	Highest Single HAP
Sterilization S1 through S7	0.38	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0.38	0.38
Sterilization S8 and S9	0.29	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0.29	0.29
Plastic Tubing & Metal Wiring	-	7.14E-03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0.01	0.01
Catheter Impregnation	-	1.23E-01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0.12	0.12
Boilers	-	-	1.84E-04	1.05E-04	6.59E-03	1.58E-01	2.99E-04	-	-	-	4.39E-05	9.66E-05	1.23E-04	3.34E-05	1.84E-04	-	0.17	0.16
Diesel Em. Generators	-	-	6.48E-03	-	6.59E-04	-	2.35E-03	1.61E-03	2.10E-04	6.58E-05	-	-	-	-	-	-	0.01	0.01
Package Prep	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	9.00E-02	0.17	0.09
	6.69E-01	1.31E-01	6.66E-03	1.05E-04	7.24E-03	1.58E-01	2.65E-03	1.61E-03	2.10E-04	6.58E-05	4.39E-05	9.66E-05	1.23E-04	3.34E-05	1.84E-04	9.00E-02	1.15	0.67
																		Ethylene Oxide

Appendix A: Potential Emission Calculations
Source Wide Ethylene Oxide (EO) Emissions by Facility

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Administrative Amendment No.: 105-41050-00030
Reviewer: Tamara Havics

Sterilization S1 through S7	Stack Vent Identification #	Fraction of EO Usage	Maximum Uncontrolled Emissions (lbs/yr) [1]	Control Efficiency (%)	Maximum Controlled Emissions (lbs/yr)
Sterilization Chamber (Vacuum) Vents	PS01	0.9500	72,000.0	99.00%	720
Sterilization Chamber Exhaust Vents (Back vents)	SV01	0.0035	260.0	99.00%	2.6
Product Transfer	SV01	0.0021	1.56	0%	1.56
Aeration (HC1 through HC14)	HV01	0.0444	3,340.0	99.00%	33.4
Total (lbs/yr)	-	1.00	75,601.56	-	757.56
Total (tons/yr)	-	-	**37.80**	-	**0.38**

Notes
(1) The Maximum Uncontrolled Emissions were calculated as follows: Potential Emissions = Fraction of EO Usage x [Maximum Production (pallets/hr) x Average EO/Pallet x 8760 hrs/yr]
The Maximum Production and Average EO/Pallet is confidential information, pursuant to 326 IAC 17.1-4
Potential Emissions for Sterilization Chambers S1 through S7 taken from FESOP Second Renewal No. F105-27381-00030, issued August 24, 2009.

Sterilization S8 and S9	Stack Vent Identification #	Fraction of EO Usage	Maximum Uncontrolled Emissions (lbs/yr) [1]	Control Efficiency (%)	Maximum Controlled Emissions (lbs/yr)
Sterilization Chamber (Vacuum) Vents	PS01	0.9500	45,671.0	99.00%	456.71
Sterilization Chamber Exhaust Vents (Back vents) [2]	CEV01, 02	0.0035	168.0	99%	1.68
Product Transfer	-	0.0021	101.0	0%	101.00
Aeration (HC1 through HC14)	HV01	0.0444	2,135.0	99.00%	21.35
Total (lbs/yr)	-	1.00	48,075.00	-	580.74
Total (tons/yr)	-	-	**24.04**	-	**0.29**

Notes
(1) The Maximum Uncontrolled Emissions were calculated as follows: Potential Emissions = Fraction of EO Usage x [Maximum Production (pallets/hr) x Average EO/Pallet x 8760 hrs/yr]
The Maximum Production and Average EO/Pallet is confidential information, pursuant to 326 IAC 17.1-4

(2) The new sterilization chambers S8 & S9 are not required to control the sterilization chamber exhaust vents (back vents), pursuant to 40 CFR 63, Subpart O (National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Emissions Standards for Sterilization Facilities). The existing units, S1 through S7, are required to control the back vents pursuant to the source's 8-1-6 BACT for these units.

The size and production rate of these sterilization chambers is approved as confidential information.

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Appendix A: Emission Calculations
VOC and Particulate
From Surface Coating, Miscellaneous Cleaning Operations, Catheter Inpregnation, and Paclitaxel Treatment

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Administrative Amendment No.: 105-41050-00030
Reviewer: Tamara Havics

State Potential Emissions (uncontrolled):

Material (as applied)	Process	Density (Lb/Gal)	Weight % Volatile (H20& Organics)	Weight % Water	Weight % Organics	Volume % Water	Volume % Non-Vol (solids)	Maximum Gal of Mat. (gal/hr)	Pounds VOC per gallon of coating less water	Pounds VOC per gallon of coating	Potential VOC pounds per hour	Potential VOC pounds per day	Potential VOC tons per year	Particulate Potential ton/yr	lb VOC /gal solids	Transfer Efficiency
Surface Coating																
(Confidential)	Plastic Tubing & Metal Wiring								7.7	7.66	0.25	6.07	1.11	0.00	197.90	100.00%
(Confidential)	Plastic Tubing								6.5	6.51	0.21	5.16	0.94	0.00	N/A	100.00%
Miscellaneous Cleaning																
(Confidential)	Miscellaneous Cleaning								6.5	6.51	2.16	51.87	9.47	0.00	N/A	100.00%
Catheter Impregnation																
(Confidential)	Catheter Impregnation								1.2	1.20	0.03	0.68	0.12	0.00	N/A	100.00%
(Confidential)	Catheter Impregnation								7.5	7.50	0.18	4.24	0.77	0.00	N/A	100.00%
Paclitaxel Treatment																
(Confidential)	Paclitaxel Treatment								6.6	6.60	0.54	13.07	2.38	0.00	N/A	100.00%
(Confidential)	Paclitaxel Treatment								6.6	6.60	0.54	13.07	2.38	0.00	N/A	100.00%
Total State Potential Emissions:											**3.92**	**94.14**	**17.18**	**0.00**		

Federal Potential Emissions (controlled):

	Control Efficiency: VOC	Control Efficiency: PM	Controlled VOC lbs per Hour	Controlled VOC lbs per Day	Controlled VOC tons per Year	Controlled PM tons/yr
Total Federal Potential Emissions:	0.00%	0.00%	**3.92**	**94.14**	**17.18**	**0.00**

Note:
Shaded boxes indicate information is confidential.

Methodology:
Pounds of VOC per Gallon Coating less Water = (Density (lb/gal) * Weight % Organics) / (1-Volume % water)
Pounds of VOC per Gallon Coating = (Density (lb/gal) * Weight % Organics)
Potential VOC Pounds per Hour = Pounds of VOC per Gallon coating (lb/gal) * Gal of Material (gal/unit) * Maximum (units/hr)
Potential VOC Pounds per Day = Pounds of VOC per Gallon coating (lb/gal) * Gal of Material (gal/unit) * Maximum (units/hr) * (24 hr/day)
Potential VOC Tons per Year = Pounds of VOC per Gallon coating (lb/gal) * Gal of Material (gal/unit) * Maximum (units/hr) * (8760 hr/yr) * (1 ton/2000 lbs)
Particulate Potential Tons per Year = (units/hour) * (gal/unit) * (lbs/gal) * (1- Weight % Volatiles) * (1-Transfer efficiency) *(8760 hrs/yr) *(1 ton/2000 lbs)
Pounds VOC per Gallon of Solids = (Density (lbs/gal) * Weight % organics) / (Volume % solids) * Transfer Efficiency
Total = Worst Coating + Sum of all solvents used
Controlled emission rate = uncontrolled emission rate * (1 - control efficiency)

Appendix A: Emission Calculations
Uncontrolled Surface Coating HAP Emissions - Potential to Emit

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Administrative Amendment No.: 105-41050-00030
Reviewer: Tamara Havics

Potential To Emit							
Material	Process	Density (lb/gal)	Maximum Gal of Mat. (gal/hr)	Weight % Methanol	Weight % MIBK	Methanol Emissions (tons/yr)	MIBK Emissions (tons/yr)
(Confidential)	Plastic Tubing & Metal Wiring					0.01	0.00
(Confidential)	Plastic Tubing					0.00	0.00
(Confidential)	Catheter Impregnation					0.12	0.00
						0.13	0.00
							0.13

Note:
Shaded boxes indicate information is confidential.

Methodology:
HAPs emission rate (tons/yr) = density (lb/gal) * (gal/unit) * (units/hour) * weight % HAP * % Flash Off * (8,760 hrs/yr) * (1 ton/2,000 lb)

Appendix A: Emissions Calculations
Natural Gas Combustion Only
MM BTU/HR <100
Insignificant Combustion
Boilers
Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Administrative Amendment No.: 105-41050-00030
Reviewer: Tamara Havics

Unit ID	MMBtu/hr
C230-F	1.68
C231-F	1.68
C232-F	7.00
C233-F	0.85
C238-F	0.45
C239-F	1.26
C240-F	1.26
C241-F	2.1349
C242-F	2.1349
C246-F	1.50
C364-F	0.50
	20.45

Heat Input Capacity MMBtu/hr	HHV mmBtu/mmscf	Potential Throughput MMCF/yr
20.45	1020	175.6

	Pollutant						
	PM*	PM10*	direct PM2.5*	SO2	NOx	VOC	CO
Emission Factor in lb/MMCF	1.9	7.6	7.6	0.6	100 **see below	5.5	84
Potential Emission in tons/yr	0.17	0.67	0.67	0.05	8.78	0.48	7.38

*PM emission factor is filterable PM only. PM10 emission factor is filterable and condensable PM10 combined.
PM2.5 emission factor is filterable and condensable PM2.5 combined.
**Emission Factors for NOx: Uncontrolled = 100, Low NOx Burner = 50, Low NOx Burners/Flue gas recirculation = 32

	HAPs - Organics				
	Benzene	Dichlorobenzene	Formaldehyde	Hexane	Toluene
Emission Factor in lb/MMcf	2.1E-03	1.2E-03	7.5E-02	1.8E+00	3.4E-03
Potential Emission in tons/yr	1.844E-04	1.054E-04	6.586E-03	1.581E-01	2.986E-04

	HAPs - Metals				
	Lead	Cadmium	Chromium	Manganese	Nickel
Emission Factor in lb/MMcf	5.0E-04	1.1E-03	1.4E-03	3.8E-04	2.1E-03
Potential Emission in tons/yr	4.391E-05	9.660E-05	1.229E-04	3.337E-05	1.844E-04

Appendix A: Emission Calculations
Large Reciprocating Internal Combustion Engines - Diesel Fuel
Output Rating (>600 HP)
Maximum Input Rate (>4.2 MMBtu/hr)

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Administrative Amendment No.: 105-41050-00030
Reviewer: Tamara Havics

Emissions calculated based on output rating (hp)

Output Horsepower Rating (hp)	4772.0
Maximum Hours Operated per Year	500
Potential Throughput (hp-hr/yr)	2,386,000
Sulfur Content (S) of Fuel (% by weight)	0.500

Emergency Diesel Generators:

Unit #1 (HP)	1850
Unit #2 (HP)	2922

	Pollutant						
	PM*	PM10*	direct PM2.5*	SO2	NOx	VOC	CO
Emission Factor in lb/hp-hr	7.00E-04	4.01E-04	4.01E-04	4.05E-03 *(.00809S)*	2.40E-02 **see below	7.05E-04	5.50E-03
Potential Emission in tons/yr	0.84	0.48	0.48	4.83	28.63	0.84	6.56

*PM10 emission factor in lb/hp-hr was calculated using the emission factor in lb/MMBtu and a brake specific fuel consumption of 7,000 Btu / hp-hr (AP-42 Table 3.3-1).
**NOx emission factor: uncontrolled = 0.024 lb/hp-hr, controlled by ignition timing retard = 0.013 lb/hp-hr

Hazardous Air Pollutants (HAPs)

	Pollutant						
	Benzene	Toluene	Xylene	Formaldehyde	Acetaldehyde	Acrolein	Total PAH HAPs***
Emission Factor in lb/hp-hr****	5.43E-06	1.97E-06	1.35E-06	5.52E-07	1.76E-07	5.52E-08	1.48E-06
Potential Emission in tons/yr	6.48E-03	2.35E-03	1.61E-03	6.59E-04	2.10E-04	6.58E-05	1.77E-03

***PAH = Polyaromatic Hydrocarbon (PAHs are considered HAPs, since they are considered Polycyclic Organic Matter)
****Emission factors in lb/hp-hr were calculated using emission factors in lb/MMBtu and a brake specific fuel consumption of 7,000 Btu / hp-hr (AP-42 Table 3.3-1).

Appendix A: Emission Calculations
Other Insignificant Activities

Company Name: Cook Incorporated
Address: 6330 North Matthews Drive, Ellettsville, Indiana 47429
Administrative Amendment No.: 105-41050-00030
Reviewer: Tamara Havics

The following emissions were calculated and approved with FESOP Second Renewal No. 105-27381-00030, issued August 24, 2009

Total Potential To Emit (tons/year)				
Emissions Generating Activity				
Pollutant	Assembly Operations	Package Prep	Marking, Printing	**TOTAL**
PM	0.14	0.00	0.00	0.14
PM10/PM2.5	0.14	0.00	0.00	0.14
SO2	0.00	0.00	0.00	0.00
NOx	0.00	0.00	0.00	0.00
VOC	0.11	0.18	0.03	0.32
CO	0.00	0.00	0.00	0.00
total HAPs	0.00	0.17	0.00	0.17
worst case single HAP	0.00	(TCE) 0.09	0.00	(TCE) 0.09

What if you are not satisfied with this decision and you want to file an appeal?

Who may file an appeal?
The decision described in the accompanying Notice of Decision may be administratively appealed. Filing an appeal is formally known as filing a "Petition for Administrative Review" to request an "administrative hearing."

If you object to this decision issued by the Indiana Department of Environmental Management (IDEM) and are: 1) the person to whom the decision was directed, 2) a party specified by law as being eligible to appeal, or 3) aggrieved or adversely affected by the decision, you are entitled to file an appeal. (An aggrieved or adversely affected person is one who would be considered by the court to be negatively impacted by the decision. If you file an appeal because you feel that you are aggrieved, it will be up to you to demonstrate in your appeal how you are directly impacted in a negative way by the decision).

The Indiana Office of Environmental Adjudication (OEA) was established by state law – see Indiana Code (IC) 4-21.5-7 – and is a separate state agency independent of IDEM. The jurisdiction of the OEA is limited to the review of environmental pollution concerns or any alleged technical or legal deficiencies associated with the IDEM decision making process. Once your request has been received by OEA, your appeal may be considered by an Environmental Law Judge.

What is required of persons filing an appeal?
Filing an appeal is a legal proceeding, so it is suggested that you consult with an attorney. Your request for an appeal must include your name and address and identify your interest in the decision (Or, if you are representing someone else, his or her name and address and their interest in the decision). In addition, please include a photocopy of the accompanying Notice of Decision or list the permit number and name of the applicant, or responsible party, in your letter.

Before a hearing is granted, you must identify the reason for the appeal request and the issues proposed for consideration at the hearing. You also must identify the permit terms and conditions that, in your judgment, would appropriately satisfy the requirements of law with respect to the IDEM decision being appealed. That is, you must suggest an alternative to the language in the permit (or other order, or decision) being appealed, and your suggested changes must be consistent with all applicable laws (See Indiana Code 13-15-6-2) and rules (See Title 315 of the Indiana Administrative Code, or 315 IAC).

The effective date of this agency action is stated on the accompanying Notice of Decision (or other IDEM decision notice). If you file a "Petition for Administrative Review" (appeal), you may wish to specifically request that the action be "stayed" (temporarily halted) because most appeals do not allow for an automatic "stay." If, after an evidentiary hearing, a "stay" is granted, the IDEM-approved action may be halted altogether, or only allowed to continue in part, until a final decision has been made regarding the appeal. However, if the action is not "stayed" the IDEM-approved activity will be allowed to continue during the appeal process.

(See reverse side)

Where can you file an appeal?
If you wish to file an appeal, you must do so in writing. There are no standard forms to fill out and submit, so you must state your case in a letter (called a petition for administrative review) to the Indiana Office of Environmental Adjudication (OEA). Do not send the original copy of your appeal request to IDEM. Instead, send or deliver your letter to:

The Indiana Office of Environmental Adjudication
100 North Senate Ave.
Indiana Government Center North
Room N103
Indianapolis, IN 46204-2273

If you file an appeal, also please send a copy of your appeal letter to the IDEM contact person identified in the Notice of Decision, and to the applicant (person receiving an IDEM permit, or other approval).

Your appeal (petition for administrative review) must be received by the Office of Environmental Adjudication in a timely manner. Different types of permit approvals have different deadlines for filing an appeal. The accompanying Notice of Decision (NOD) explains how to determine the due date for filing an appeal for this particular permit decision. To ensure that you meet this filing requirement, your appeal request must be:

1) Delivered in person to the OEA by the close-of-business on the due date. (If the due date falls on a day when the Office of Environmental Adjudication (OEA) is closed for the weekend or for a state holiday, then your petition will be accepted on the next business day on which OEA is open.); or
2) Given to a private carrier who will deliver it to the OEA on your behalf, (and from whom you must obtain a receipt dated on or before the due date); or
3) For those appeal requests sent by U.S. Mail, your letter must be postmarked by no later than midnight of the due date; or
4) Faxed to the OEA at 317/233-9372 before the close-of-business of the due date, provided that the original signed "Petition for Administrative Review" is also sent, or delivered, to the OEA in a timely manner.

What are the costs associated with filing an appeal?
The OEA does not charge a fee for filing documents for an administrative review or for the use of its hearing facilities. However, OEA does charge a fifteen cent ($.15) per page fee for copies of any documents you may request. Another cost that could be associated with your appeal would be for attorney's fees. Although you have the option to act as your own attorney, the administrative review and associated hearing are complex legal proceedings; therefore, you should consider whether your interests would be better represented by an experienced attorney.

What can you expect from the Office of Environmental Adjudication (OEA) after you file for an appeal?
The OEA will provide you with notice of any prehearing conferences, preliminary hearings, hearings, "stays," or orders disposing of the review of this decision. In addition, you may contact the OEA by phone at 317/233-0850 or via email at Frontdesk@OEA.IN.GOV with any scheduling questions. However, technical questions should be directed to IDEM at the number indicated on the Notice of Decision.

Do not expect to discuss details of your case with the OEA other than in a formal setting such as a prehearing conference, a formal hearing, or a settlement conference. The OEA is not allowed to discuss a case without all sides being present. All parties to the proceeding are expected to appear at the initial prehearing conference.

APPENDIX B

GC CALIBRATION DATA

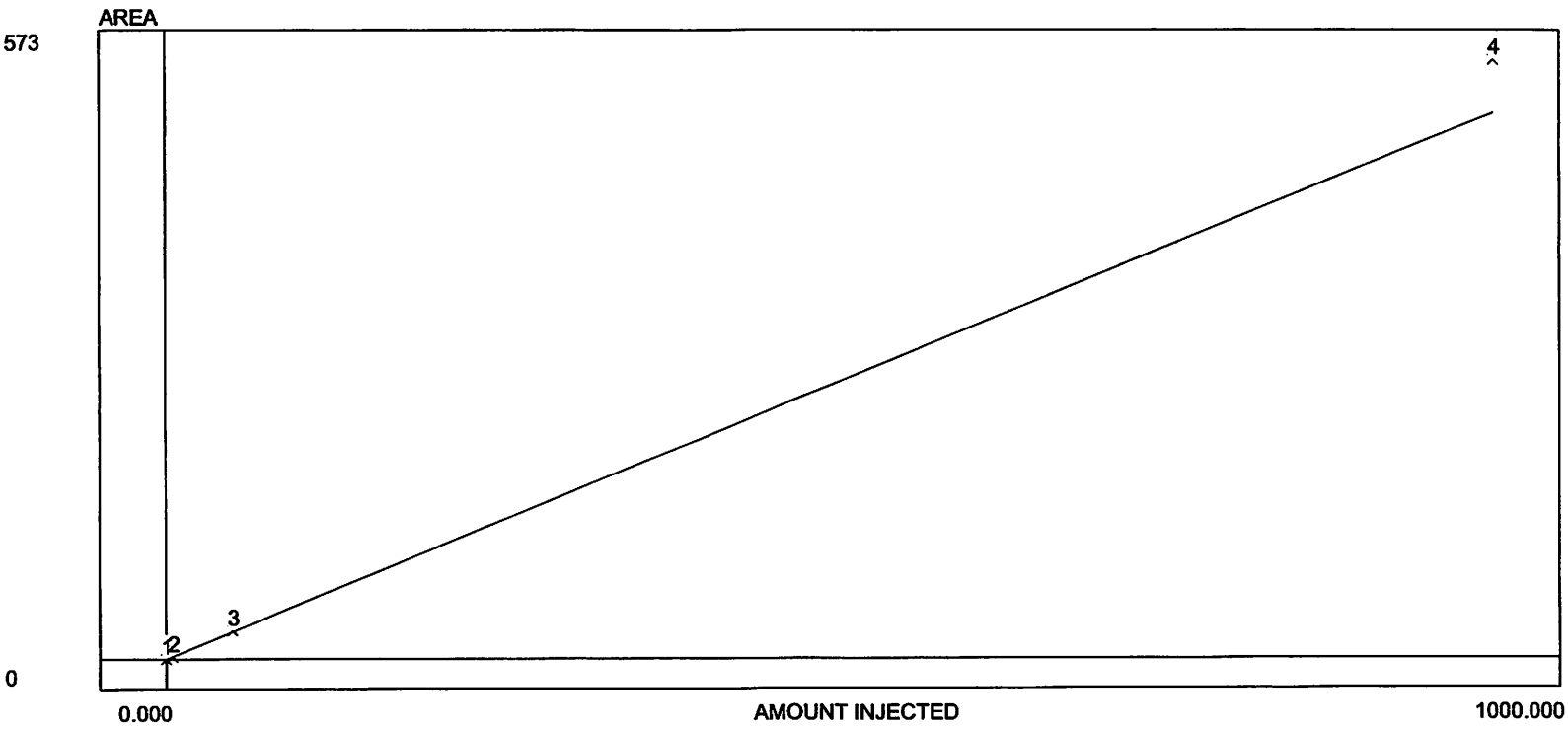
Confidential Business Information

Component file: eto1-100.cpt

Peak	Name	Start	End	Calibration	Int.Std	Units
1	Dead Vol / Air	0.000	0.300		0.000	
2	Ambient H2O	0.300	0.420		0.000	
3	Ethylene Oxide	0.420	0.520	C:\peak359\1Cool0.000.cappm		
4	Acetaldehyde	0.520	0.800		0.000	
5	CO2	0.800	1.000		0.000	

May 29th 2018 Calibration Data

Calibration file: C:\peak359\1Cook2019.cal



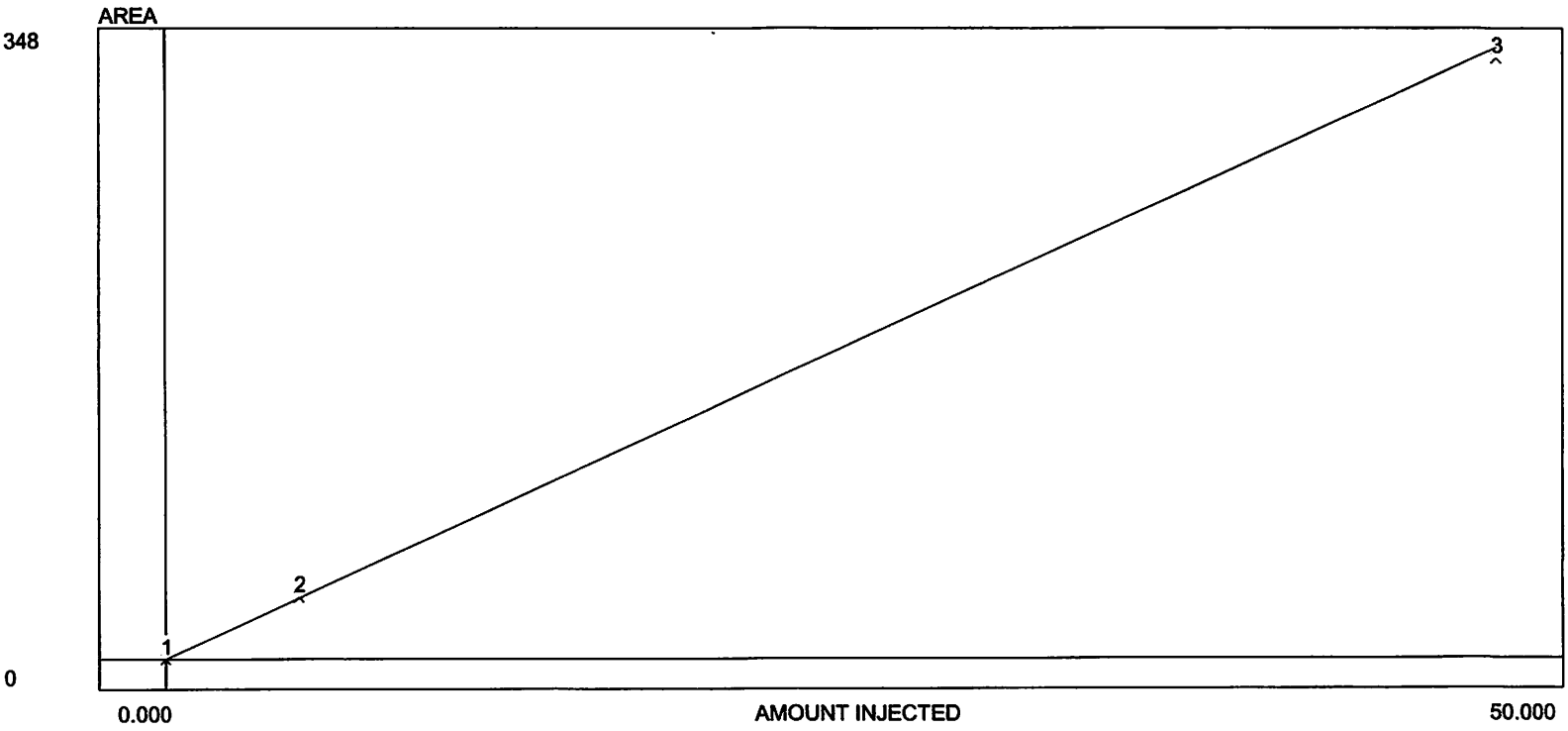
Avg slope of curve: 0.52
Y-axis intercept: 0.00
Linearity: 1.00
Number of levels: 4
SD/rel SD of CF's: 0.3/68.1
Y=0.5217X
r2: 1.0000
Last calibrated: Mon May 20 11:36:27 2019

Lvl.	Area/ht.	Amount	CF	Current	Previous #1	Previous #2
1	0.000	0.000	0.000	0.000	N/A	N/A
2	2.240	5.000	0.448	2.240	N/A	N/A
3	27.200	50.000	0.544	27.200	N/A	N/A
4	573.000	1000.000	0.573	573.000	N/A	N/A

Component file: eto2-100.cpt

Peak	Name	Start	End	Calibration	Int.Std	Units
1	* Dead Vol / Air	0.000	0.300		0.000	
2	Ambient H2O	0.300	0.400		0.000	
3	Ethylene Oxide	0.400	0.520	C:\peak359\2Cool0.000.cappm		
4	Acetaldehyde	0.520	0.800		0.000	
5	CO2	0.800	1.000		0.000	

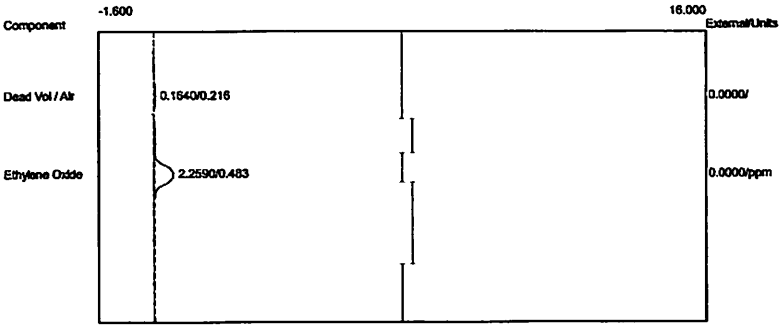
Calibration file: C:\peak359\2Cook2019.cal



Avg slope of curve: 7.08
Y-axis intercept: 0.00
Linearity: 1.00
Number of levels: 3
SD/rel SD of CF's: 4.1/86.6
Y=7.0800X
r2: 1.0000
Last calibrated: Mon May 20 11:29:24 2019

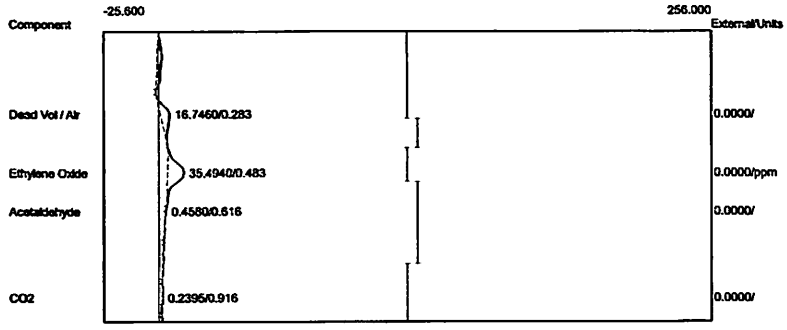
Lvl.	Area/ht.	Amount	CF	Current	Previous #1	Previous #2
1	0.000	0.000	0.000	0.000	N/A	N/A
2	36.000	5.000	7.200	36.000	N/A	N/A
3	348.000	50.000	6.960	348.000	N/A	N/A

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: PreCal
Analysis date: 05/20/2019 10:31:19
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-C01.CHR (c:\peak359)
Sample: 5 ppm EtO std
Operator: D. Kremer



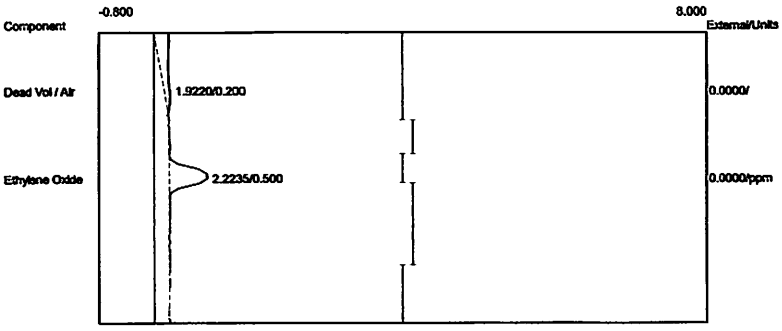
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	0.1640	0.0000	
Ethylene Oxide	0.483	2.2590	0.0000	ppm
		2.4230	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: PreCal
Analysis date: 05/20/2019 10:31:19
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-C01.CHR (c:\peak359)
Sample: 5 ppm EtO std
Operator: D. Kremer



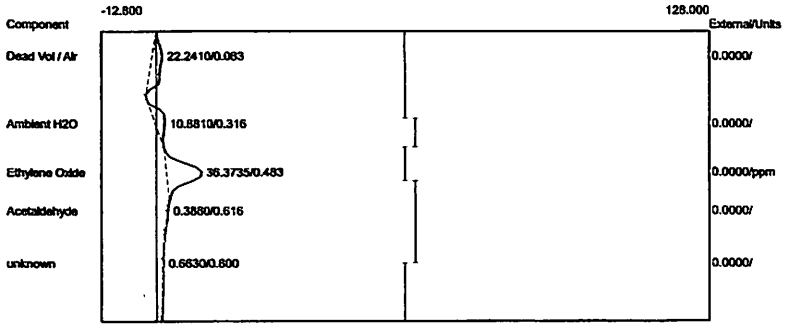
Component	Retention	Area	External	Units
Dead Vol / Air	0.283	16.7460	0.0000	
Ethylene Oxide	0.483	35.4940	0.0000	ppm
Acetaldehyde	0.616	0.4580	0.0000	
CO2	0.916	0.2395	0.0000	
		52.9375	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: PreCal
Analysis date: 05/20/2019 10:35:19
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-C02.CHR (c:\peak359)
Sample: 5 ppm EtO std
Operator: D. Kremer



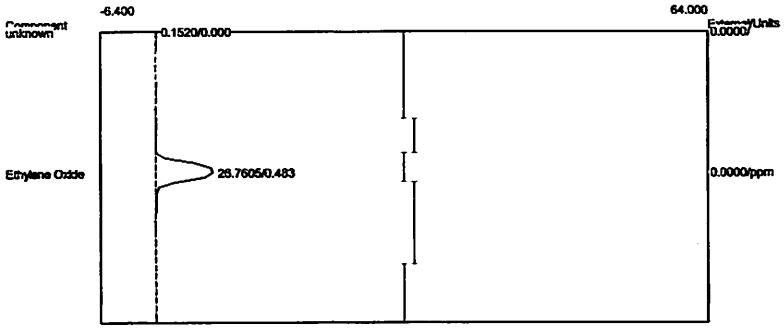
Component	Retention	Area	External	Units
Dead Vol / Air	0.200	1.9220	0.0000	
Ethylene Oxide	0.500	2.2235	0.0000	ppm
		4.1455	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: PreCal
Analysis date: 05/20/2019 10:35:19
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-C02.CHR (c:\peak359)
Sample: 5 ppm EtO std
Operator: D. Kremer



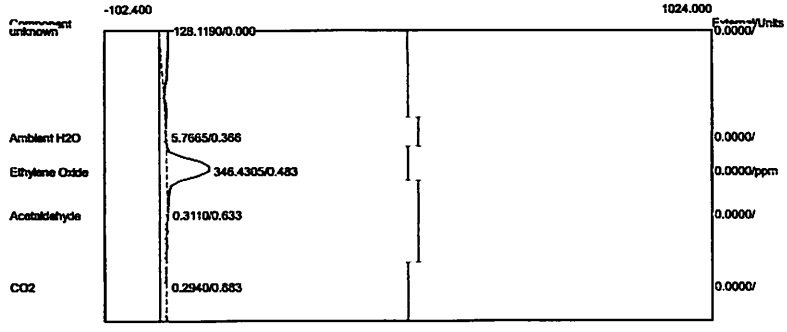
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	22.2410	0.0000	
Ambient H2O	0.316	10.8810	0.0000	
Ethylene Oxide	0.483	36.3735	0.0000	ppm
Acetaldehyde	0.616	0.3880	0.0000	
		69.8835	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: PreCal
Analysis date: 05/20/2019 11:10:39
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-C03.CHR (c:\peak359)
Sample: 50 ppm EtO std
Operator: D. Kremer



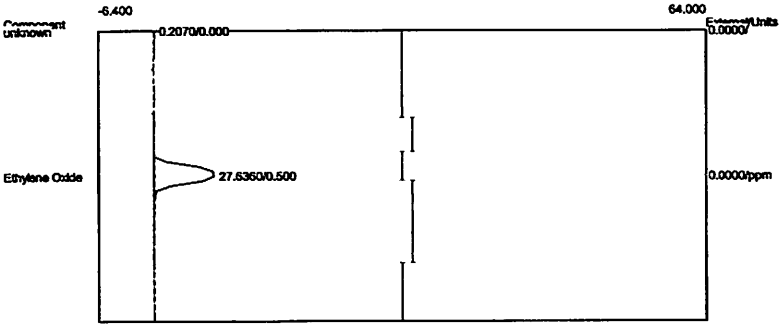
Component	Retention	Area	External	Units
Ethylene Oxide	0.483	26.7605	0.0000	ppm
		26.7605	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: PreCal
Analysis date: 05/20/2019 11:10:39
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-C03.CHR (c:\peak359)
Sample: 50 ppm EtO std
Operator: D. Kremer



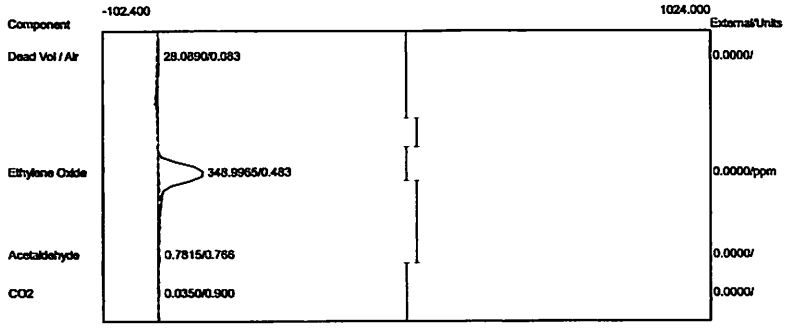
Component	Retention	Area	External	Units
Ambient H2O	0.366	5.7665	0.0000	
Ethylene Oxide	0.483	346.4305	0.0000	ppm
Acetaldehyde	0.633	0.3110	0.0000	
CO2	0.883	0.2940	0.0000	
		352.8020	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: PreCal
Analysis date: 05/20/2019 11:13:42
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-C04.CHR (c:\peak359)
Sample: 50 ppm EtO std
Operator: D. Kremer



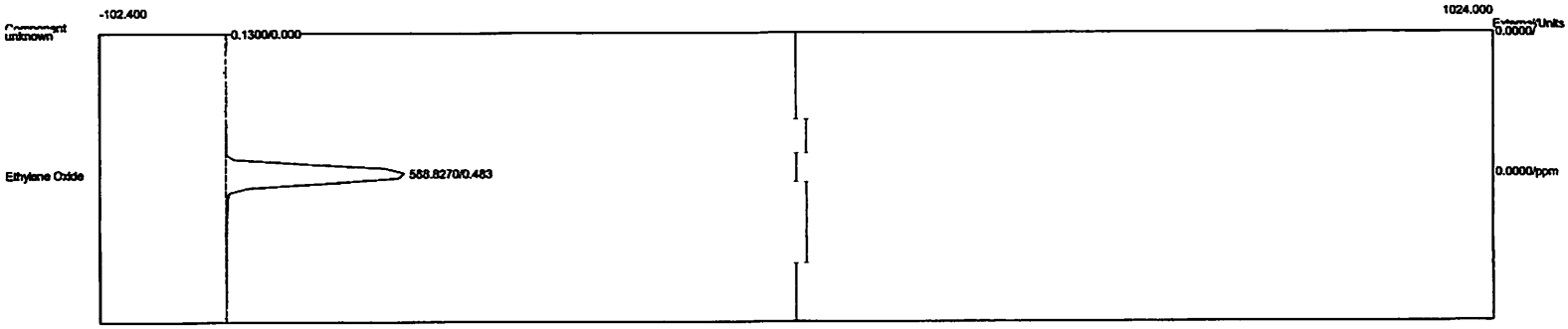
Component	Retention	Area	External	Units
Ethylene Oxide	0.500	27.6360	0.0000	ppm
		27.6360	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: PreCal
Analysis date: 05/20/2019 11:13:42
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-C04.CHR (c:\peak359)
Sample: 50 ppm EtO std
Operator: D. Kremer



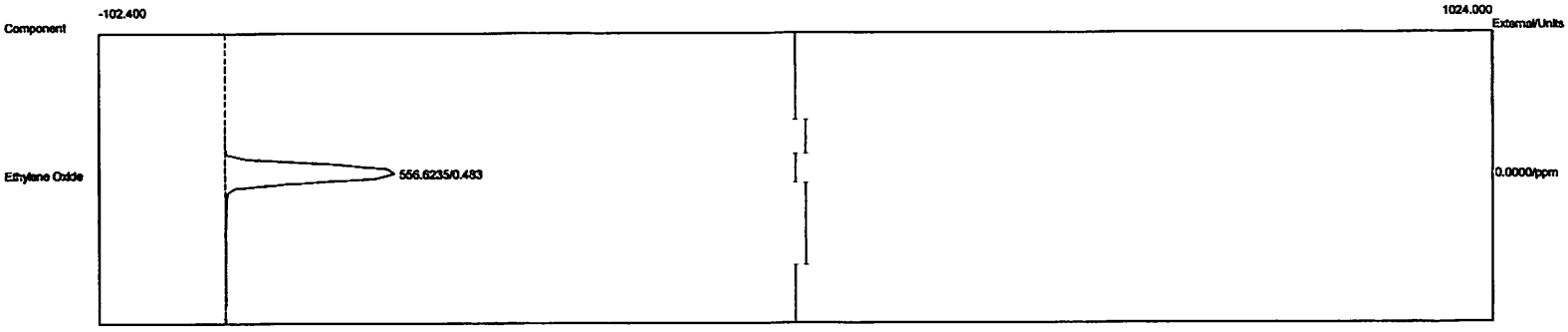
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	28.0890	0.0000	
Ethylene Oxide	0.483	348.9965	0.0000	ppm
Acetaldehyde	0.766	0.7815	0.0000	
CO2	0.900	0.0350	0.0000	
		377.9020	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: PreCal
Analysis date: 05/20/2019 11:27:28
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-C05.CHR (c:\peak359)
Sample: 1000 ppm EtO std
Operator: D. Kremer



Component	Retention	Area	External	Units
Ethylene Oxide	0.483	588.8270	0.0000	ppm
		588.8270	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: PreCal
Analysis date: 05/20/2019 11:31:35
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-C06.CHR (c:\peak359)
Sample: 1000 ppm EtO std
Operator: D. Kremer



Component	Retention	Area	External	Units
Ethylene Oxide	0.483	556.6235	0.0000	ppm
		556.6235	0.0000	

APPENDIX C

SUPPORTING CHROMATOGRAMS

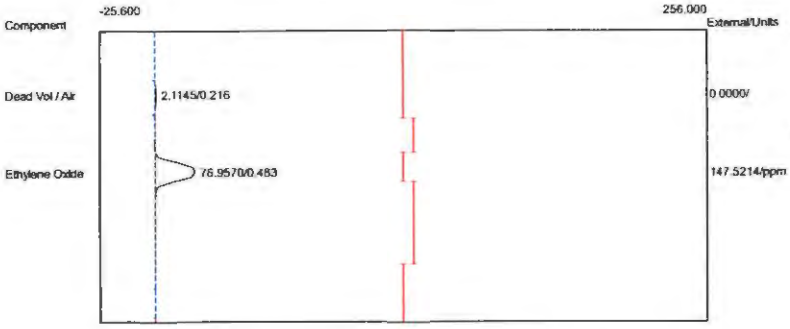
Confidential Business Information

Performance Demonstration 1

Chamber S9

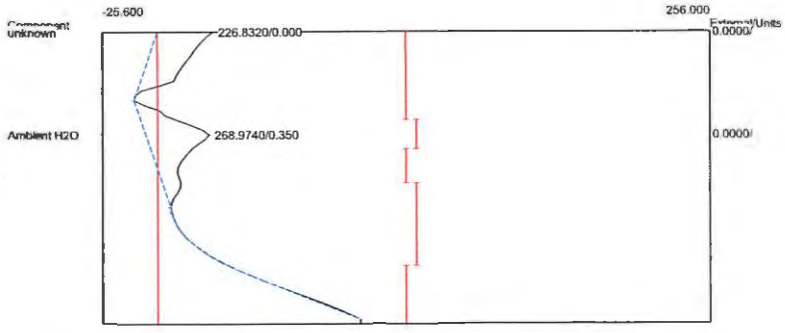
Confidential Business Information

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:22:04
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D13.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1145	0.0000	
Ethylene Oxide	0.483	76.9570	147.5214	ppm
		79.0715	147.5214	

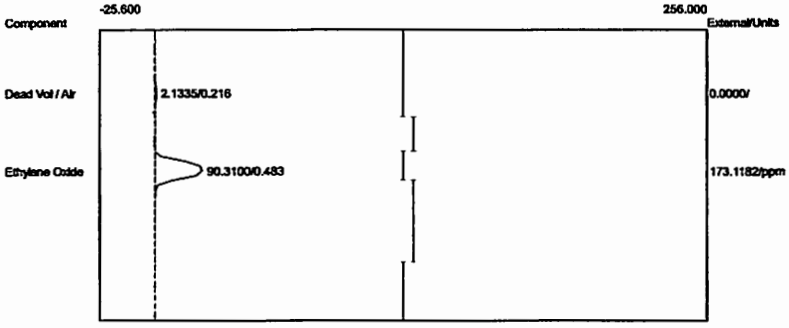
Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:22:04
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D13.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Ambient H2O	0.350	268.9740	0.0000	
		268.9740	0.0000	

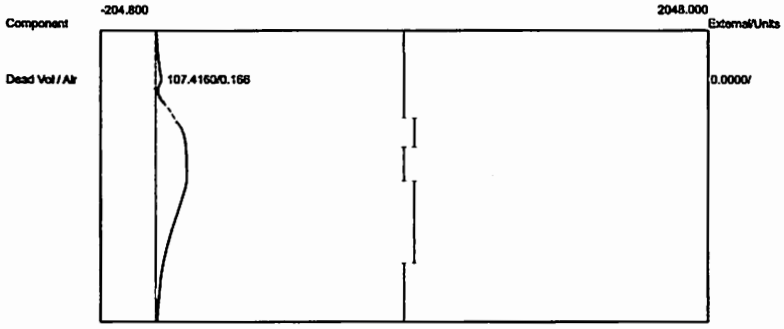
May 20th BV & Dry Bed testing Ch. 59 Drainage
20 min exposure -6425FPM 22" Duct

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:20:09
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D12.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



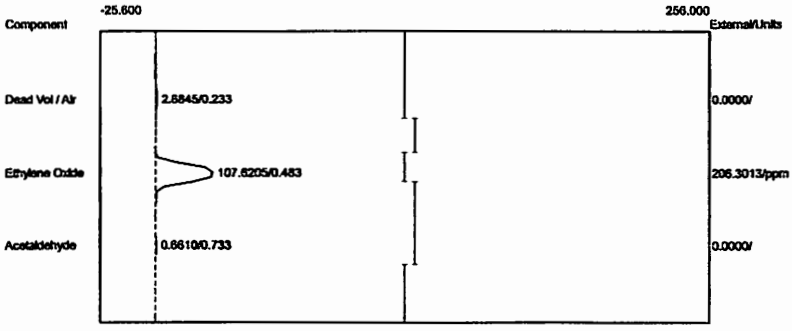
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1335	0.0000	
Ethylene Oxide	0.483	90.3100	173.1182	ppm
		92.4435	173.1182	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:20:09
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D12.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



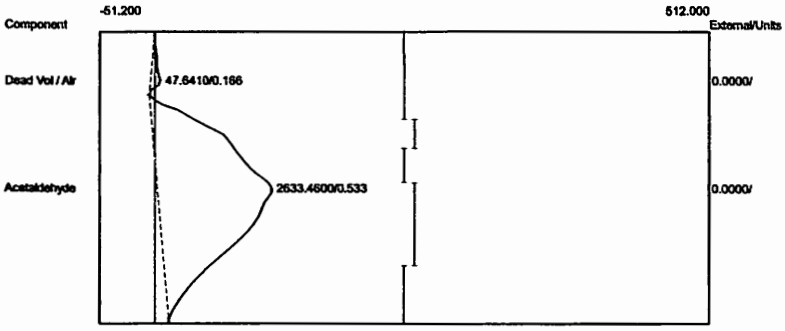
Component	Retention	Area	External	Units
Dead Vol / Air	0.166	107.4160	0.0000	
		107.4160	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:17:42
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D11.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



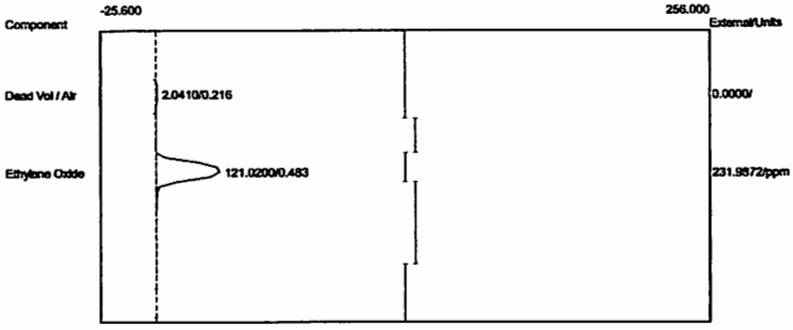
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.8845	0.0000	
Ethylene Oxide	0.483	107.6205	206.3013	ppm
Acetaldehyde	0.733	0.6610	0.0000	
		111.1660	206.3013	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:17:42
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D11.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



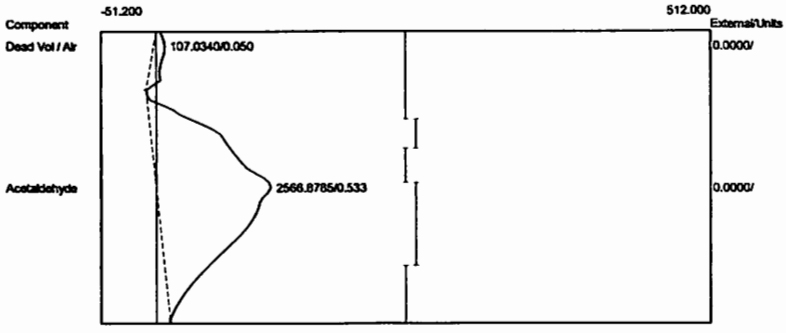
Component	Retention	Area	External	Units
Dead Vol / Air	0.166	47.6410	0.0000	
Acetaldehyde	0.533	2633.4600	0.0000	
		2681.1010	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:16:30
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D10.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



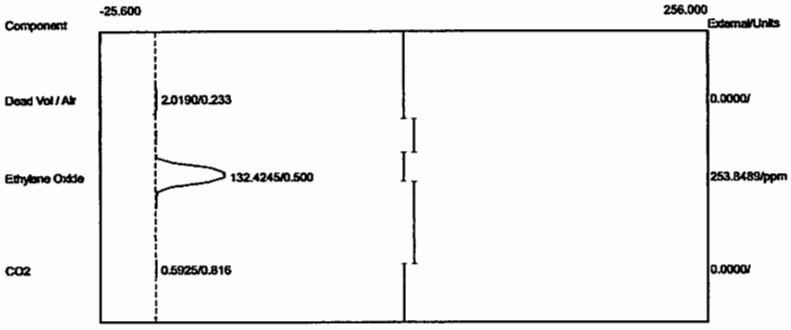
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.0410	0.0000	
Ethylene Oxide	0.483	121.0200	231.9872	ppm
		123.0610	231.9872	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:16:30
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D10.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



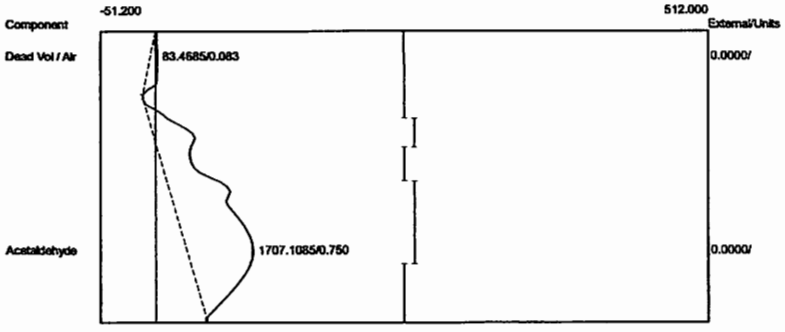
Component	Retention	Area	External	Units
Dead Vol / Air	0.050	107.0340	0.0000	
Acetaldehyde	0.533	2566.8785	0.0000	
		2673.9125	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:15:06
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D09.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



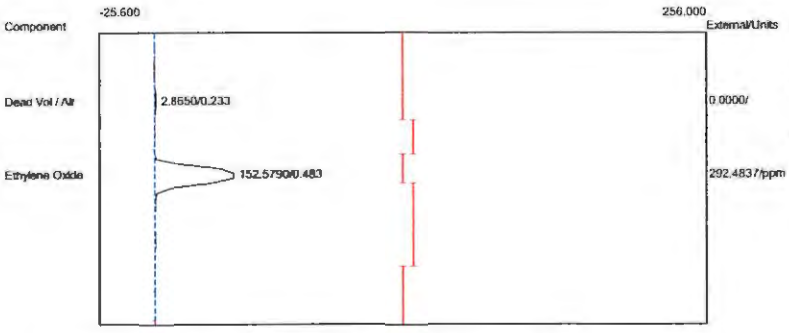
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.0190	0.0000	
Ethylene Oxide	0.500	132.4245	253.8489	ppm
CO2	0.816	0.5925	0.0000	
		135.0360	253.8489	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:15:06
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D09.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



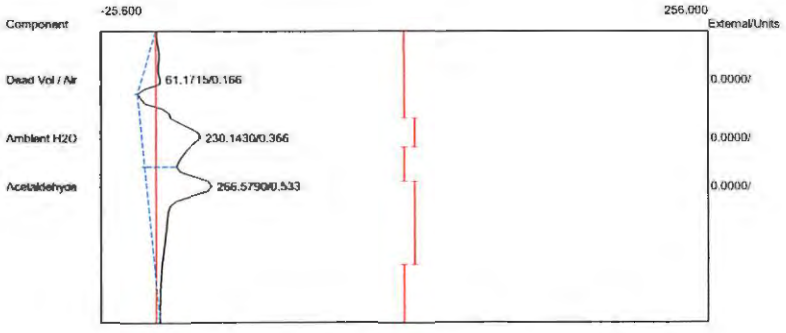
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	83.4685	0.0000	
Acetaldehyde	0.750	1707.1085	0.0000	
		1790.5770	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:13:58
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D08.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



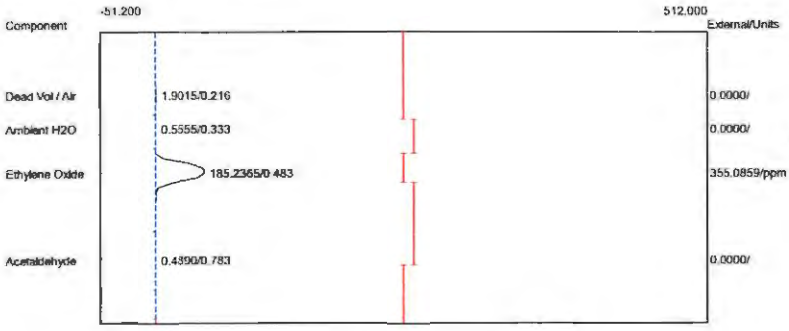
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.8650	0.0000	
Ethylene Oxide	0.483	152.5790	292.4837	ppm
		155.4440	292.4837	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:13:58
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D08.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



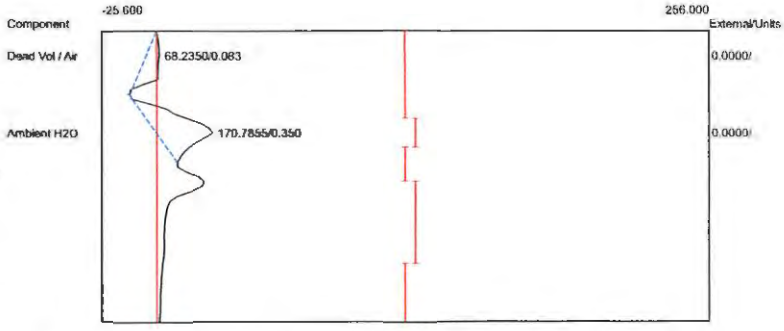
Component	Retention	Area	External	Units
Dead Vol / Air	0.166	61.1715	0.0000	
Ambient H2O	0.366	230.1430	0.0000	
Acetaldehyde	0.533	266.5790	0.0000	
		557.8935	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:12:44
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D07.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



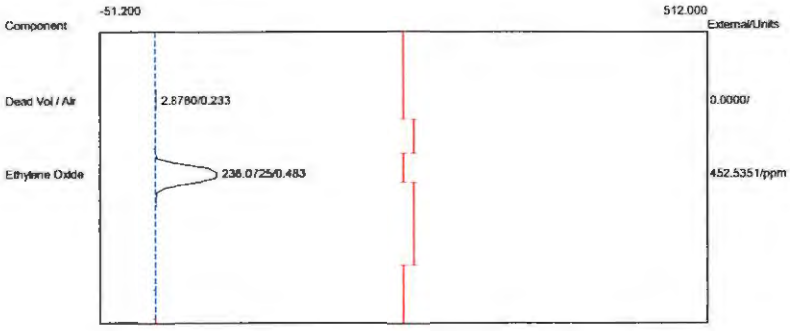
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	1.9015	0.0000	
Ambient H2O	0.333	0.5555	0.0000	
Ethylene Oxide	0.483	185.2365	355.0859	ppm
Acetaldehyde	0.783	0.4890	0.0000	
		188.1825	355.0859	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:12:44
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D07.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



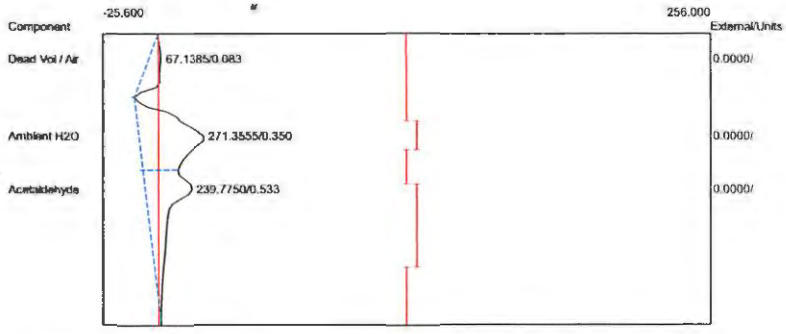
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	68.2350	0.0000	
Ambient H2O	0.350	170.7855	0.0000	
		239.0205	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:11:35
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D06.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



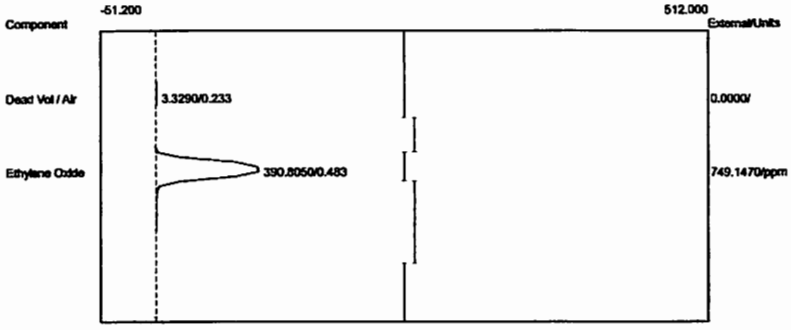
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.8780	0.0000	
Ethylene Oxide	0.483	236.0725	452.5351	ppm
		238.9505	452.5351	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:11:35
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D06.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



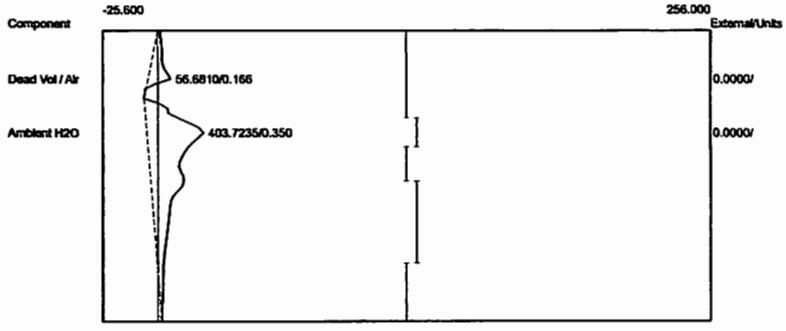
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	67.1385	0.0000	
Ambient H2O	0.350	271.3555	0.0000	
Acetaldehyde	0.533	239.7750	0.0000	
		578.2690	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:10:23
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D05.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



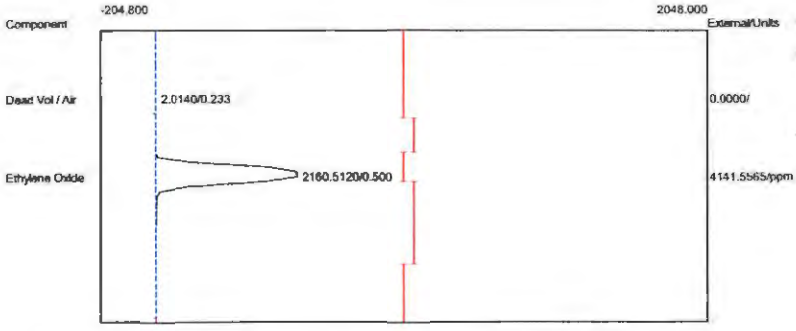
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	3.3290	0.0000	
Ethylene Oxide	0.483	390.8050	749.1470	ppm
		394.1340	749.1470	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:10:23
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D05.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



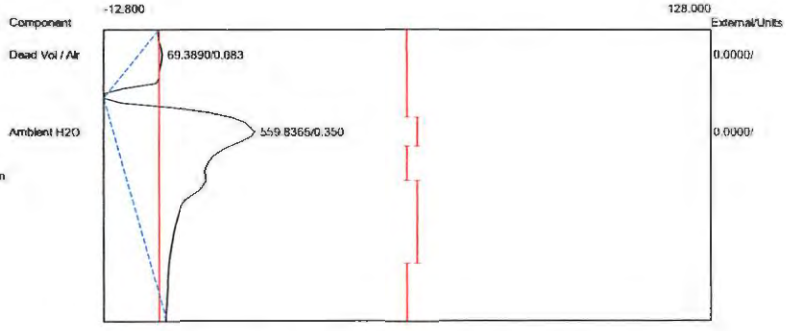
Component	Retention	Area	External	Units
Dead Vol / Air	0.166	56.6810	0.0000	
Ambient H2O	0.350	403.7235	0.0000	
		460.4045	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:09:08
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D04.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.0140	0.0000	
Ethylene Oxide	0.500	2160.5120	4141.5565	ppm
		2162.5260	4141.5565	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV
Analysis date: 05/20/2019 14:09:08
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D04.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.083	69.3890	0.0000	
Ambient H2O	0.350	559.8365	0.0000	
		629.2255	0.0000	

Performance Demonstration 2

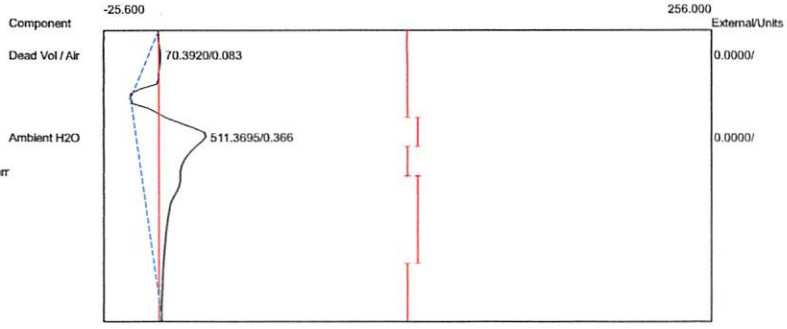
Chamber S8

Confidential Business Information

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV S-8
Analysis date: 05/20/2019 14:38:41
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D18.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer

Component	Retention	Area	External	Units
Dead Vol / Air	0.233	1.7700	0.0000	
Ambient H2O	0.350	0.1060	0.0000	
Ethylene Oxide	0.483	6006.1245	11513.3377	ppm
		6008.0005	11513.3377	

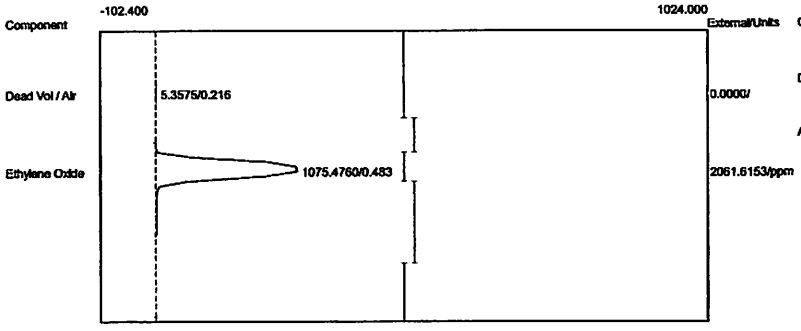
Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV - S8
Analysis date: 05/20/2019 14:38:41
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D14.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.083	70.3920	0.0000	
Ambient H2O	0.366	511.3695	0.0000	
		581.7615	0.0000	

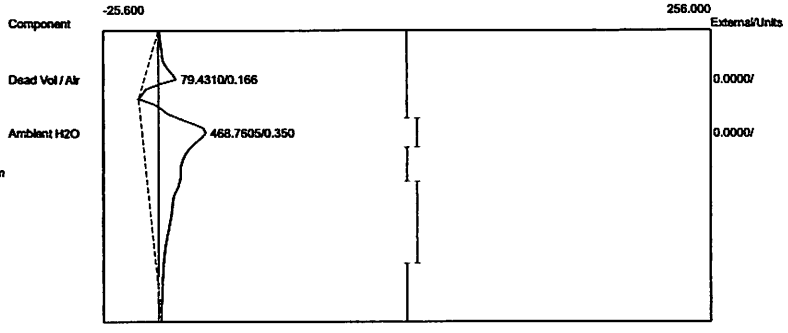
chamber S8 Back vent testing using Dunnage
May 20th. Flow 647.15 FPM

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV S-8
Analysis date: 05/20/2019 14:39:57
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D19.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



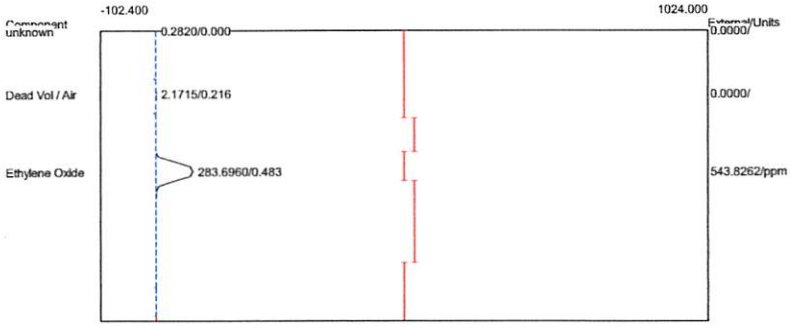
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	5.3575	0.0000	
Ethylene Oxide	0.483	1075.4760	2061.6153	ppm
		1080.8335	2061.6153	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV - S8
Analysis date: 05/20/2019 14:39:57
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D15.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



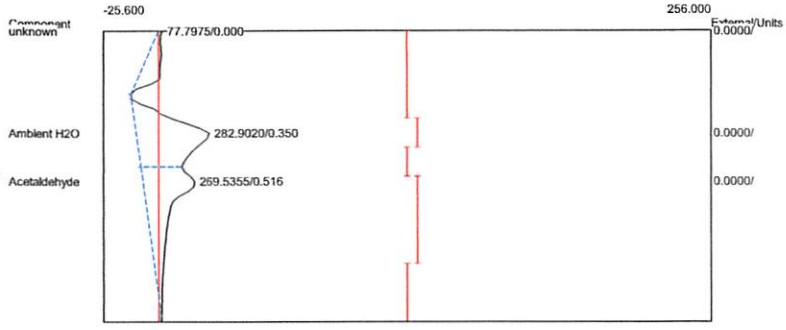
Component	Retention	Area	External	Units
Dead Vol / Air	0.166	79.4310	0.0000	
Ambient H2O	0.350	468.7605	0.0000	
		548.1915	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV S-8
Analysis date: 05/20/2019 14:41:28
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D20.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



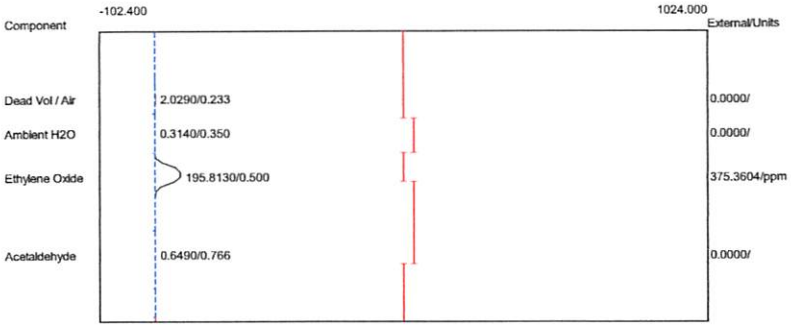
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1715	0.0000	
Ethylene Oxide	0.483	283.6960	543.8262	ppm
		285.8675	543.8262	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV - S8
Analysis date: 05/20/2019 14:41:28
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D16.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



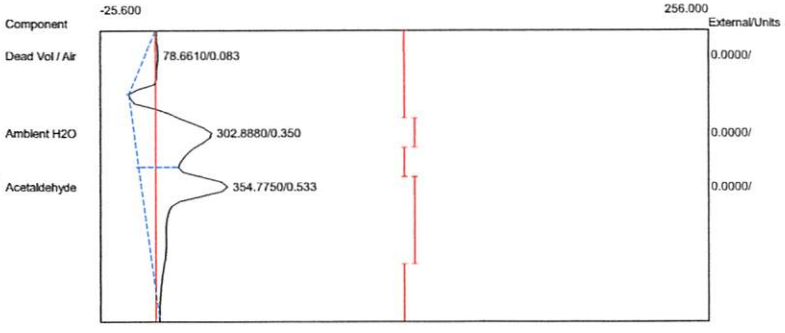
Component	Retention	Area	External	Units
Ambient H2O	0.350	282.9020	0.0000	
Acetaldehyde	0.516	269.5355	0.0000	
		552.4375	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV S-8
Analysis date: 05/20/2019 14:42:38
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D21.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



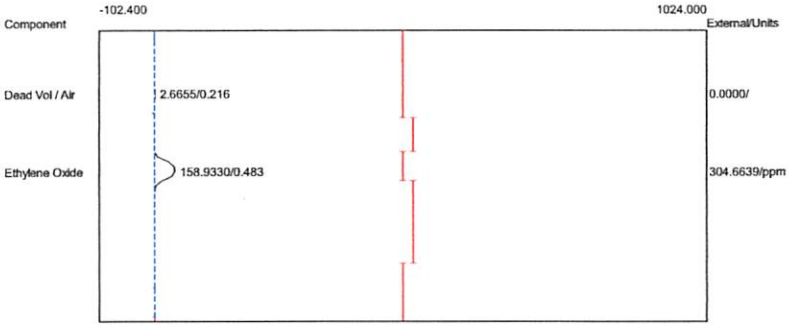
Component	Retention	Area	External	Units
Dead Vol / Air	0.233	2.0290	0.0000	
Ambient H2O	0.350	0.3140	0.0000	
Ethylene Oxide	0.500	195.8130	375.3604	ppm
Acetaldehyde	0.766	0.6490	0.0000	
		198.8050	375.3604	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV - S8
Analysis date: 05/20/2019 14:42:38
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D17.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



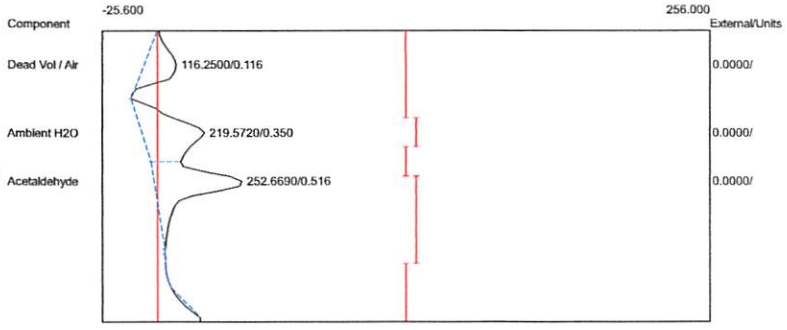
Component	Retention	Area	External	Units
Dead Vol / Air	0.083	78.6610	0.0000	
Ambient H2O	0.350	302.8880	0.0000	
Acetaldehyde	0.533	354.7750	0.0000	
		736.3240	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV S-8
Analysis date: 05/20/2019 14:43:58
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D22.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



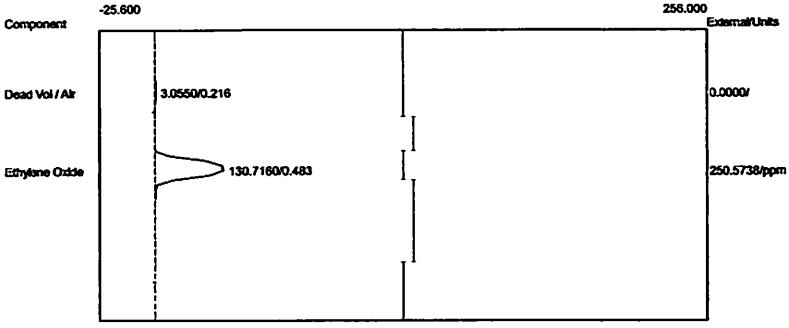
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.6655	0.0000	
Ethylene Oxide	0.483	158.9330	304.6639	ppm
		161.5985	304.6639	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV - S8
Analysis date: 05/20/2019 14:43:58
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D18.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



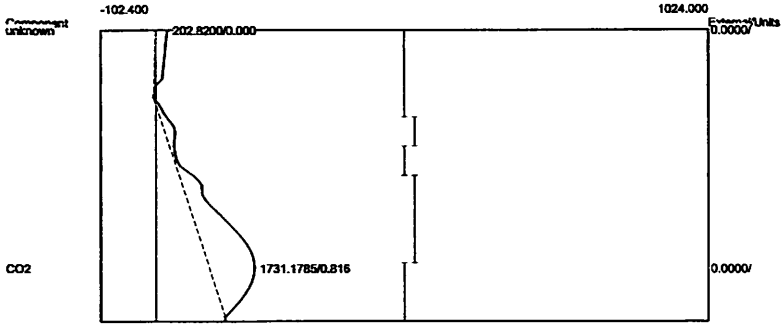
Component	Retention	Area	External	Units
Dead Vol / Air	0.116	116.2500	0.0000	
Ambient H2O	0.350	219.5720	0.0000	
Acetaldehyde	0.516	252.6690	0.0000	
		588.4910	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV S-8
Analysis date: 05/20/2019 14:45:46
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D23.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



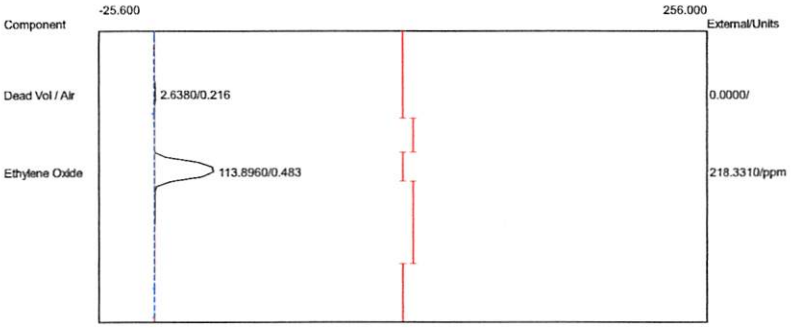
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	3.0550	0.0000	
Ethylene Oxide	0.483	130.7160	250.5738	ppm
		133.7710	250.5738	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV - S8
Analysis date: 05/20/2019 14:45:46
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D19.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



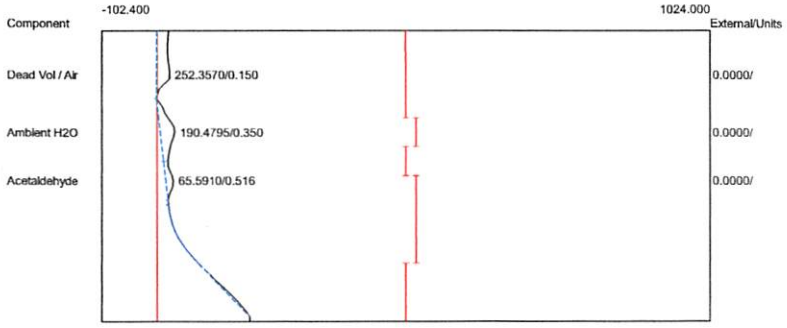
Component	Retention	Area	External	Units
CO2	0.816	1731.1785	0.0000	
		1731.1785	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV S-8
Analysis date: 05/20/2019 14:47:04
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D24.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



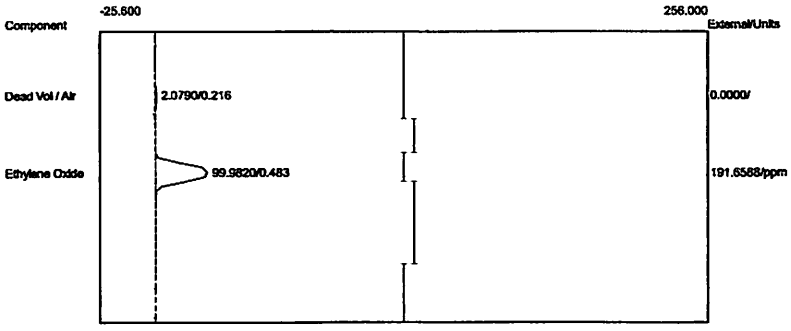
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.6380	0.0000	
Ethylene Oxide	0.483	113.8960	218.3310	ppm
		116.5340	218.3310	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV - S8
Analysis date: 05/20/2019 14:47:04
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D20.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



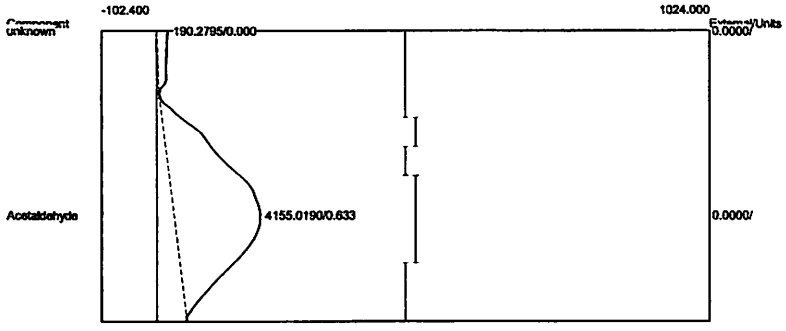
Component	Retention	Area	External	Units
Dead Vol / Air	0.150	252.3570	0.0000	
Ambient H2O	0.350	190.4795	0.0000	
Acetaldehyde	0.516	65.5910	0.0000	
		508.4275	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV S-8
Analysis date: 05/20/2019 14:48:37
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D25.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.0790	0.0000	
Ethylene Oxide	0.483	99.9820	191.6588	ppm
		102.0610	191.6588	

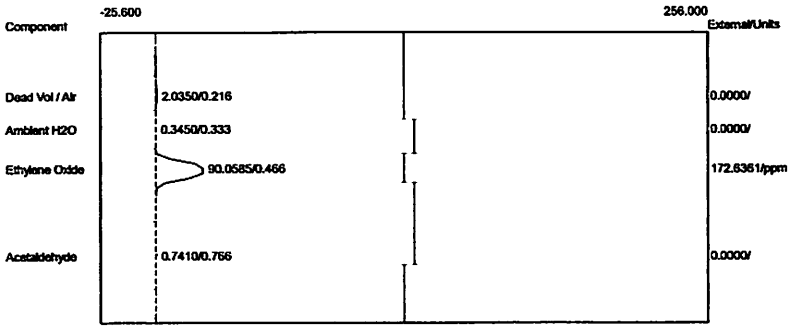
Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV - S8
Analysis date: 05/20/2019 14:48:37
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D21.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer

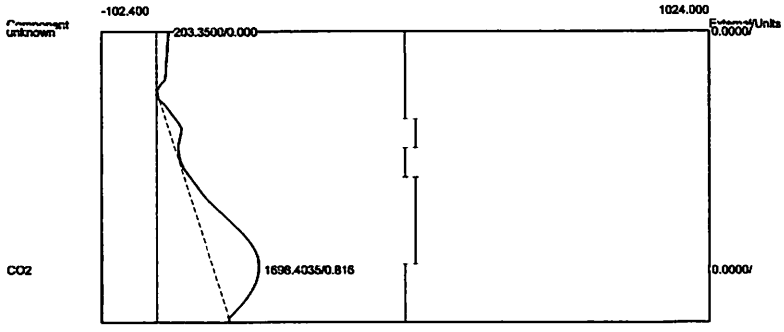


Component	Retention	Area	External	Units
Acetaldehyde	0.633	4155.0190	0.0000	
		4155.0190	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV S-8
Analysis date: 05/20/2019 14:49:46
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D26.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV - S8
Analysis date: 05/20/2019 14:49:46
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D22.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer

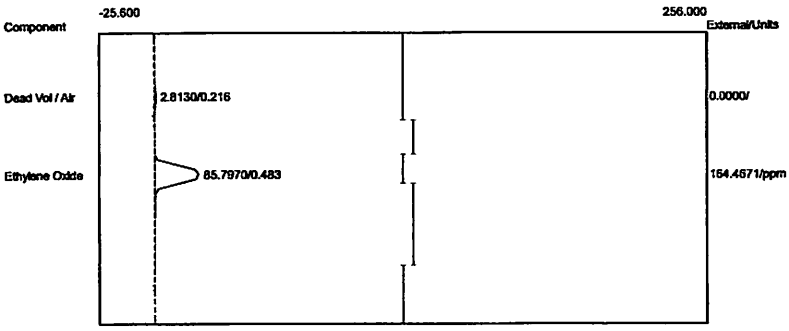




Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.0350	0.0000	
Ambient H2O	0.333	0.3450	0.0000	
Ethylene Oxide	0.466	90.0585	172.6361	ppm
Acetaldehyde	0.766	0.7410	0.0000	
		93.1795	172.6361	

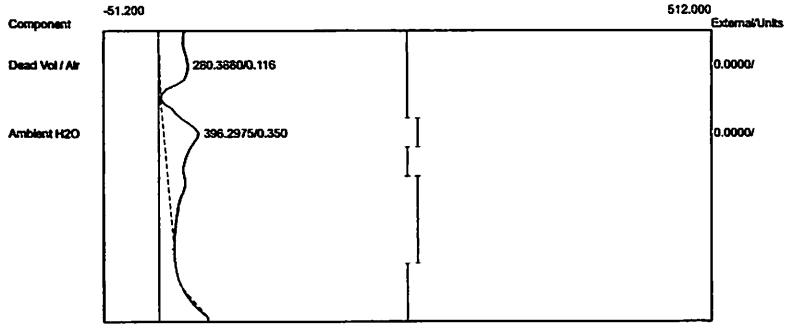
Component	Retention	Area	External	Units
CO2	0.816	1698.4035	0.0000	
		1698.4035	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV S-8
Analysis date: 05/20/2019 14:51:06
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D27.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



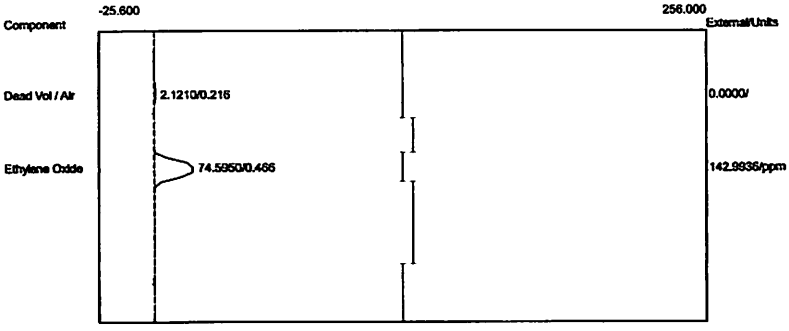
Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.8130	0.0000	
Ethylene Oxide	0.483	85.7970	164.4671	ppm
		88.6100	164.4671	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV - S8
Analysis date: 05/20/2019 14:51:06
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D23.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



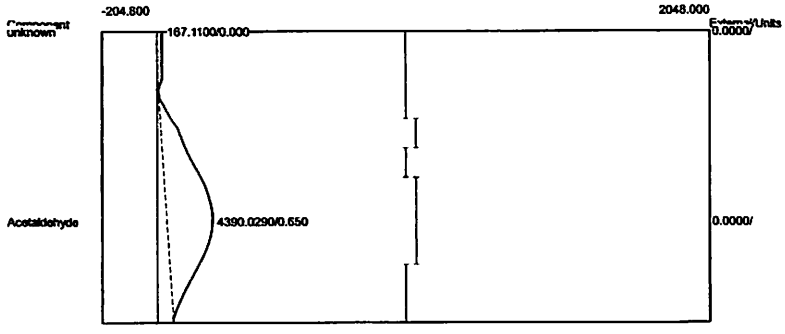
Component	Retention	Area	External	Units
Dead Vol / Air	0.116	280.3880	0.0000	
Ambient H2O	0.350	396.2975	0.0000	
		676.6855	0.0000	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV S-8
Analysis date: 05/20/2019 14:53:03
Method: Direct Injection
Description: CHANNEL 1 - FID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto1-100.cpt
Data file: 1Cook2019-D28.CHR (c:\peak359)
Sample: Dry Bed Inlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Dead Vol / Air	0.216	2.1210	0.0000	
Ethylene Oxide	0.466	74.5950	142.9936	ppm
		76.7160	142.9936	

Lab name: ECSi
Client: Cook Medical, Inc.
Client ID: BV - S8
Analysis date: 05/20/2019 14:53:03
Method: Direct Injection
Description: CHANNEL 2 - PID
Column: 1% SP-1000, Carbopack B
Carrier: HELIUM
Temp. prog: eto-100.tem
Components: eto2-100.cpt
Data file: 2Cook2019-D24.CHR (c:\peak359)
Sample: Dry Bed Outlet
Operator: D. Kremer



Component	Retention	Area	External	Units
Acetaldehyde	0.650	4390.0290	0.0000	
		4390.0290	0.0000	

APPENDIX D

PERFORMANCE TEST PHOTOGRAPHY

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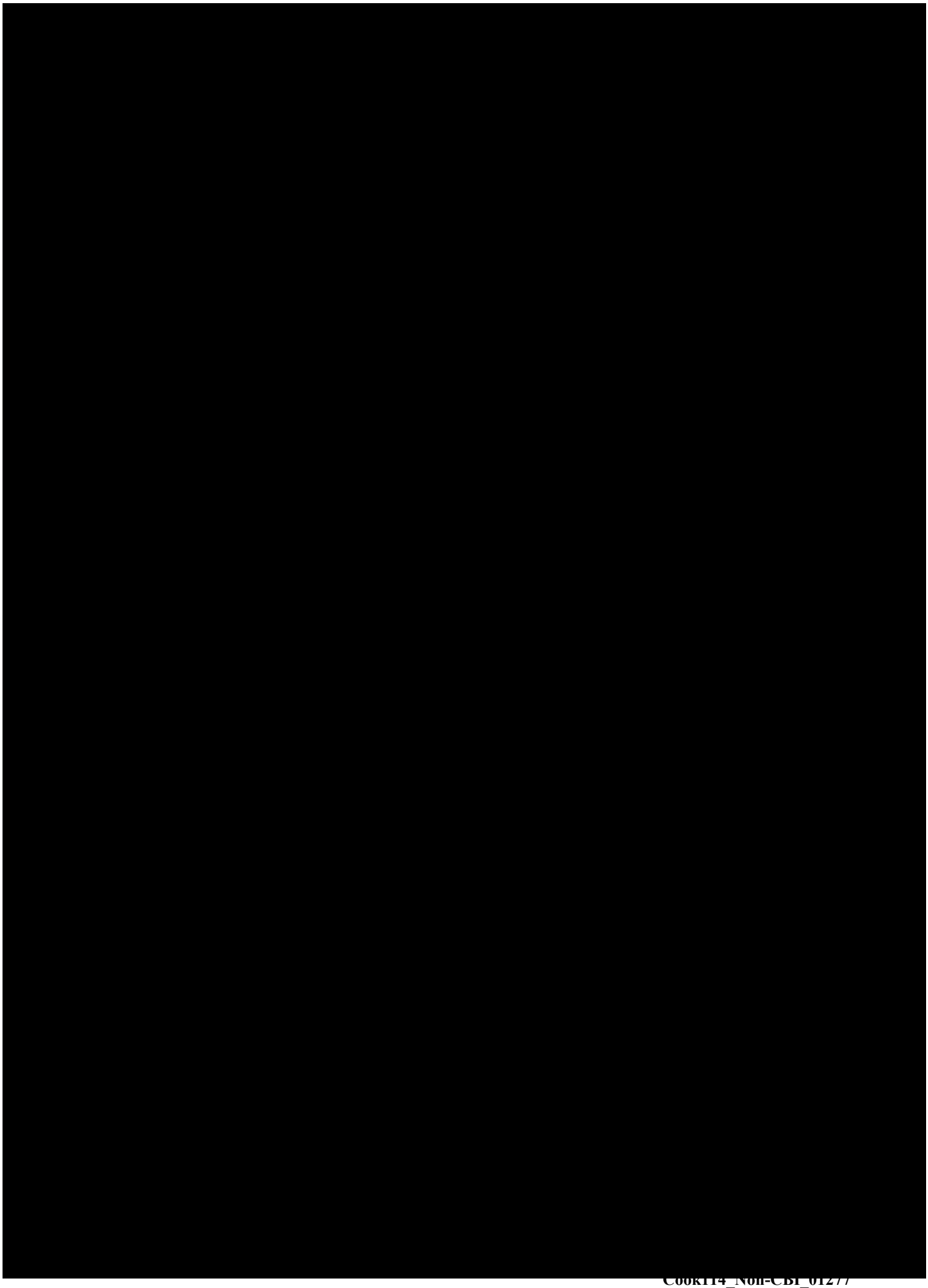

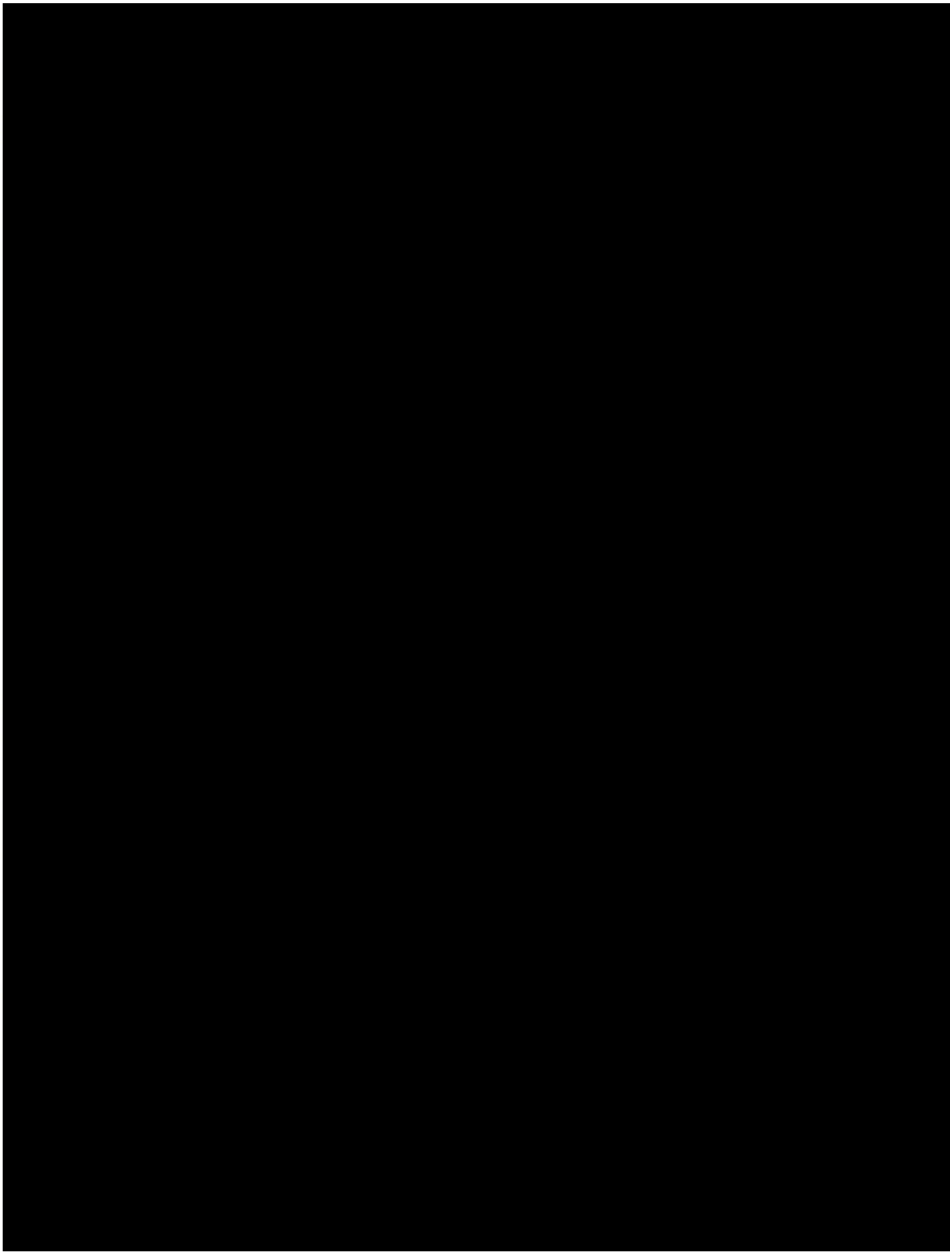

APPENDIX E

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Confidential Business Information